cobas c 111 system

Operator's Manual
Version 3.0

Document information

Revision history

Manual version	Software version	Revision date	Changes
1.0		July 2006	First publication.
2.0	2.0	December 2007	Full mode added. Improved calibration concept. Additional maintenance and troubleshooting information. Additions, improvements, and corrections.
3.0	3.0	June 2009	Inventory, processing sequence, and ratio functions added. Improvements and corrections. Layout upgraded.

Edition notice

The **cobas c** 111 instrument is a continuous random-access analyzer intended for the in vitro determination of clinical chemistry and electrolyte parameters in serum, plasma, urine or whole blood (HbA1c). It is optimized for small throughput workloads of approximately samples per day, utilizing photometric analysis and an optional unit for ion selective electrodes (ISE).

This manual is for users of the **cobas c** 111 instrument.

Every effort has been made to ensure that all the information contained in this manual is correct at the time of printing. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument will render the warranty or service agreement null and void.

Software updates are done by service representatives.

Intended use

The **cobas c** 111 instrument is a continuous random-access analyzer intended for the in vitro determination of clinical chemistry and electrolyte parameters in serum, plasma, urine or whole blood (HbA1c).

It is important that the operators read this manual thoroughly before using the system.

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Instrument approvals

The **cobas c** 111 instrument meets the protection requirements laid down in IVD Directive 98/79/EC and the European Standard EN 591. Furthermore, our instruments are manufactured and tested according to the following international standards:

- EN/IEC 61010-1 2nd Edition
- EN/IEC 61010-2-101 1st Edition

The Operator's manual meets the European Standard EN 591.

Regulatory compliance is demonstrated by the following marks:

CE — Complies with European Union (EU) Directive 98/79/EC.

c UL us — Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

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Preface

The **cobas c** 111 instrument is a continuous random-access analyzer intended for the in vitro determination of clinical chemistry and electrolyte parameters in serum, plasma, urine or whole blood (HbA1c). It is optimized for small throughput workloads of approximately samples per day, utilizing photometric analysis and an optional unit for ion selective electrodes (ISE).

This manual describes the **cobas c** 111 features and general operational concepts, and it provides operating, maintenance, and emergency procedures.

How to use this manual

- Keep this Operator's Manual in a safe place to ensure that it is not damaged and remains available for use.
- This Operator's Manual should be easily accessible at all times.

To help you find information quickly, there is a table of contents at the beginning of the manual and each chapter. In addition, a complete index can be found at the end.

Online Help system

The **cobas c** 111 instrument has a context-sensitive online Help feature to aid in its operating. "Context-sensitive" means that wherever you are located within the **cobas c** 111 software, choosing Help ( ) displays Help text relating to that area of the software. The online Help offers a quick and convenient way of finding information, such as explanations of screens and dialog boxes and on how to perform particular tasks.

Conventions used in this manual

Visual cues are used to help locate and interpret information in this manual quickly. This section explains the formatting conventions used in this manual.

Symbols The following symbols are used:

Symbol	Used for
►	Start of procedure
•	List item
👁	Cross-reference
☞	Call-up (software navigation path)
	Color of display item on the screen
	Tip
	Safety alert
	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE. The symbol denotes that the equipment must not be disposed of in the municipal waste system.

Buttons When used for identification purposes, a generic form of the buttons is used, without color or navigation indicators.

Screenshots The screen representations shown in this publication are for illustrative purposes only. The screens do not necessarily show valid data.

Abbreviations The following abbreviations are used:

Abbreviation	Definition
C	
Cfas	Calibrator for automated systems
D	
DIL	Diluent
DM	Data management
DRAM	Dynamic random access memory
E	
e.g.	*Exempli gratia* – for example
EMC	Electromagnetic compatibility
EN	European standard
I	
i.e.	*Id est* – that is to say
IEC	International Electrical Commission
ISE	Ion selective electrode
L	
LED	Light-emitting diode
LIS	Laboratory information system
LLD	Liquid level detection
N	
n/a	Not applicable
Q	
QC	Quality control
R	
REF	Reference solution for ISE unit
ROM	Read only memory
S	
SD	Standard deviation
SRAM	Static random access memory

Units

Abbreviation	Description
°C	degree centigrade
µL	microliter
µm	micrometer
A	ampère
cm	centimeter
h	hour
Hz	hertz
LB	pound (weight)
in	inch
kg	kilogram
kVA	kilo volt-ampere
L	liter
m	meter
MB	megabytes
min	minute
mL	milliliter
mm	millimeter
nm	nanometer
s	second
V	volt
VA	volt-ampère
V AC	volt alternating current
V DC	volt direct current
W	watt

System Description A

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2 Introduction to the instrument A-15
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Safety

Protecting yourself and the environment

In this chapter, you will find information on the safe operation of the **cobas c** 111 instrument.

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Safety classification

Before you attempt to use the **cobas c** 111 instrument, you must be fully familiar with the following symbols and their meanings:

WARNING

Warning

Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Caution

Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.

NOTICE

Notice

Indicates a hazardous situation which, if not avoided, may result in property damage.

Safety information

Before operating the **cobas c** 111 instrument, it is essential that you both read and understand the safety information listed below.

Read all Roche safety notices carefully and make sure you understand them.

Transport

WARNING

Injury from heavy loads

You may injure your hands, fingers, or back when putting the analyzer in place. Carry the analyzer according to the transport instructions.

Electrical safety

WARNING

Electrical shock by electronic equipment

Do not attempt to work in any electronic compartment. Installation, service, and repair must only be performed by authorized and qualified personnel.

Electrical safety

Connect the analyzer to grounded power outlets only (IEC protection class 1). All peripheral devices that are connected to the **cobas c** 111 instrument must comply with safety standard IEC 60950 for information technology equipment, or with IEC 61010-1, UL 61010-1 for laboratory use instruments.

Optical safety

WARNING

Loss of sight

The intense light of the LEDs may severely damage you eyes. Do not stare into the LEDs.

Scanning equipment using LED technology is covered by the international standard IEC 60825-1 LED Safety: Class 1.

Mechanical safety

WARNING

Personal injury or damage to the analyzer due to contact with instrument mechanism

Do not touch moving parts during instrument operation.

Instrument covers

WARNING

Personal injury or damage to the analyzer due to contact with instrument mechanism

Keep all covers closed, operate them as instructed on the screen.

Operation and maintenance

WARNING

Personal injury or damage to the analyzer due to contact with instrument mechanism

Do not touch any parts of the instrument other than those specified. During operation and maintenance of the instrument, proceed according to the instructions.

Biohazardous materials

WARNING

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Waste

WARNING

Infection by waste solution

Contact with waste solution may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Reagents and other working solutions

WARNING

Injury through reagents and other working solutions

Direct contact with reagents, cleaning solutions, or other working solutions may cause personal injury.

When handling reagents, exercise the precautions required for handling laboratory reagents, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.

Skin inflammation caused by reagents

Direct contact with reagents may cause skin irritation, inflammation, or burns.

When handling reagents, be sure to wear protective equipment and observe the cautions given in the package insert.

Installation

WARNING

Incorrect results or damage to the analyzer due to wrong installation

Follow the specified installation instructions carefully.

Environmental conditions

WARNING

Incorrect results or damage to the analyzer due to heat and humidity

Use the instrument indoor only.

For details on the required environmental conditions, see *Environmental conditions* on page A-66.

Power interruption

NOTICE

Data loss or damage to the system due to voltage drop

By a power failure or momentary voltage drop the operation unit or software of this system may get damaged or data loss may occur. Use only uninterruptible power supply.

Electromagnetic devices

WARNING

Malfunction of instrument and incorrect results due to interfering electromagnetic fields

Devices that emit electromagnetic waves may cause the instrument to malfunction. Do not operate the following devices in the same room where the system is installed:

- Mobile phone
- Transceiver
- Cordless phone
- Other electrical devices that generate electromagnetic waves

NOTICE

Instructions for in vitro diagnostic (IVD) equipment for professional use

The IVD equipment complies with the emission and immunity requirements described in the particular requirements for IVD medical equipment of the EN/IEC 61326-2-6 standard.

The electromagnetic environment should be evaluated prior to operation of the device.

Class B FCC rule compliance

This equipment has been tested and found to comply with the limits for Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interferences when the equipment is operated in a residential area. However, this equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the present manual, may cause harmful interference to radio communications.

The electromagnetic environment should be evaluated prior to operation of the device.

Approved parts

WARNING

Malfunction of instrument and incorrect results due to nonapproved parts

Use of nonapproved parts or devices may result in malfunction of the instrument and may render the warranty null and void. Only use parts and devices approved by Roche Diagnostics.

Third-party software

WARNING

Malfunction of instrument and incorrect results due to third-party software

Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior of the system. Do not install any nonapproved software.

Operator qualification

WARNING

Incorrect results or damage to the analyzer due to wrong operation

Operators are required to have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to trained service representatives.
- Follow standard laboratory practices, especially when working with biohazard material.

Operation over an extended period of time

CAUTION

Fatigue due to long hours of operation

Looking at the monitor screen over an extended period of time may lead to fatigue of your eyes or body. Take a rest for 10 to 15 minutes every hour to relax. Avoid spending more than 6 hours per day looking at the monitor screen.

Cross contamination of sample

WARNING

Incorrect results due to carryover

Traces of analytes or reagents may be carried over one test to the next. Take adequate measures (e.g. sample aliquoting) to safeguard additional testing and to avoid potentially false results.

Insoluble contaminants in sample

WARNING

Incorrect results and interruption of analysis due to contaminated samples

Insoluble contaminants in samples may cause clogging or pipetting volume shortage and deterioration in measurement accuracy. When loading samples on the instrument, make sure that samples contain no insoluble contaminants such as fibrin or dust.

Spillage

NOTICE

Malfunction due to spilled liquid

Any liquid spilled on the instrument may result in malfunction of the instrument. If liquid does spill on the instrument, wipe it up immediately and apply disinfectant.

Data security

CAUTION

Unauthorized access and data loss due to malicious software and hacker attacks

Portable storage media can be infected with and transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The **cobas c** 111 is not protected against malicious software and hacker attacks.

The customers are responsible for IT security of their IT infrastructure and for protecting it against malicious software and hacker attacks. Failure to do so may result in data loss or render the **cobas c** 111 unusable.

Roche recommends the following precautions:

- Allow connection to authorized external devices only.
- Ensure that all external devices are protected by appropriate security software.
- Ensure that access to all external devices is protected by appropriate security equipment.
- Do not copy or install any software on the **cobas c** 111 unless it is part of the system software or you are instructed to do so by a Roche service representative.
- If additional software is required, contact your Roche service representative to ensure validation of the software in question.
- Do not use the USB ports to connect other storage devices unless you are instructed to do so by official user documentation or a Roche service representative.
- Exercise utmost care when using external storage devices such as USB flash drives, CDs, or DVDs. Do not use them on public or home computers while connecting to the **cobas c** 111.
- Keep all external storage devices in a secure place and ensure that they can be accessed by authorized persons only.

For further information, contact your Roche service representative.

License notices

WARNING

Malfunction of instrument and incorrect results due to software modifications by the customer

The **cobas c** 111 instrument uses open source software. Among other things, the holders of the proprietary rights grant licenses under the terms of the GNU General Public Licence (GPL edition 2 or above) as well as under the GNU Lesser General Public License (LGPL).

The **cobas c** 111 instrument has been designed to be operated with the unmodified software as shipped. The user assumes full responsibility for changing any part of the open source software, which excludes any liability of Roche Diagnostics Ltd.

This program is distributed without any warranty; without even the implied warranty of merchantability or fitness for a particular purpose. See the GNU General Public License for more details (www.gnu.org/copyleft/gpl.html).

The source code of the used open source software is part of MIKRAPs CPUX255LCDNET board support package and may be obtained from SYSGO (http://www.sysgo.com/products/board-support-packages/).

Legal liability

Roche Diagnostics Ltd. assumes only limited liability when using the **cobas c** 111 instrument in conjunction with the **cobas c** 111 Development Channel Programming Software.

For detailed information on this matter refer to the latest version of the Development Channel Registration Form **cobas c** 111 and the **cobas c** 111 Development Channel Operator's Manual.

Disposal recommendation

All electrical and electronic products should be disposed of separately from the municipal waste system. Proper disposal of your old appliance prevents potential negative consequences for the environment and human health.

Disposal label

Electrical and electronic equipment marked with this symbol are covered by the European directive on waste electrical and electronic equipment (WEEE) 2002/96/EC.

The symbol denotes that the equipment must not be disposed of in the municipal waste system.

Disposal of external components

External components such as the scanner and the ISE power supply, which are marked with the crossed-out wheeled bin symbol, are covered by the European Directive 2002/96/EC (WEEE).

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old products, contact your city office, waste disposal service or your local service representative.

Disposal of the instrument

WARNING

The instrument must be treated as biologically contaminated hazardous waste. Final disposal must be organized in a way that does not endanger waste handlers. As a rule, such equipment must be sterile before it is passed on for final disposal.

For more information contact your local service representative.

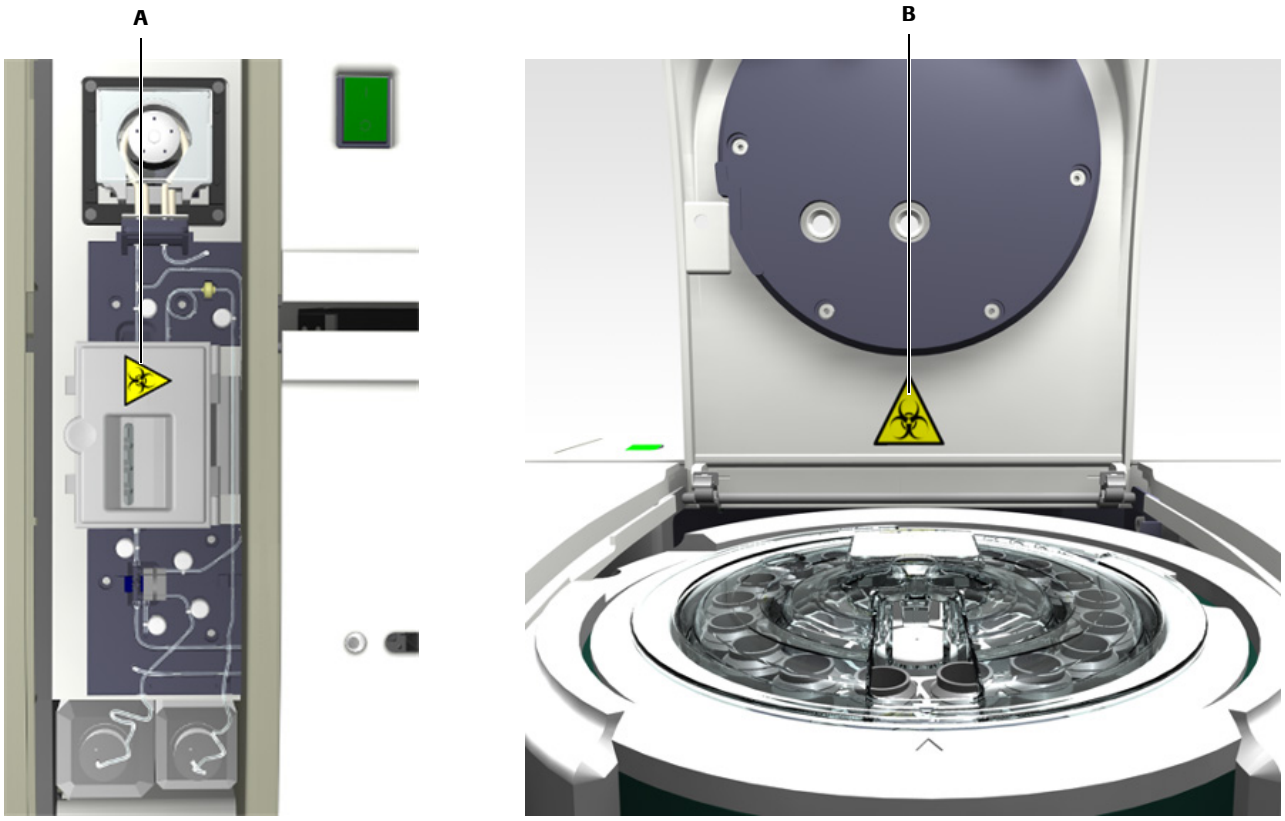
Constraint

It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat in the same way as the instrument.

Safety labels

Read all safety labels on the instrument and equipment.

The following illustration shows where on the instrument labels are displayed.



A This label on the electrode block of the ISE unit indicates that there is a danger of hazardous situations arising within the vicinity of this label, which may result in death or serious injury. The relevant laboratory procedures on safe use must be observed.
(You will find this label only if an ISE unit is installed.)

B This label on the main cover indicates that there are potential biohazards within the vicinity of this label, which may result in death or serious injury.
The relevant laboratory procedures on safe use must be observed.

Figure A-1 Safety labels on the **cobas c** 111 instrument

In addition to safety labels on the instrument, there are safety notes in the corresponding parts of the Operator's Manual.

These safety notes give more detailed information about potentially hazardous situations that may arise during daily operation or when carrying out maintenance procedures.

When working with the instrument, be sure to observe both the safety labels on the instrument and the safety notes in the Operator's Manual.

Introduction to the instrument

What you need to know before you start

In this chapter, you will find basic information on the features that are relevant for working with the **cobas c** 111 instrument.

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Overview A-22
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Overview

The **cobas c** 111 instrument is a continuous random-access analyzer intended for the in vitro determination of clinical chemistry and electrolyte parameters in serum, plasma, urine or whole blood (HbA1c). It is optimized for small throughput workloads of approximately samples per day, utilizing photometric analysis and an optional unit for ion selective electrodes (ISE).

Only trained personnel working in a professional laboratory environment may operate the **cobas c** 111 instrument.

WARNING

Incorrect results or damage to the analyzer due to wrong operation

Operators are required to have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to trained service representatives.
- Follow standard laboratory practices, especially when working with biohazard material.

Features

As part of the **cobas** family of instruments, the **cobas c** 111 instrument offers small laboratories the following advantages:

- High analytical performance

  The same bulk reagents, 12-wavelength photometer and disposable cuvettes generate results that are highly correlated to other cobas instruments.

- Efficient operation

  Cooled, exchangeable reagent disks ensure economical reagent use; disposable cuvette segments allow for easy cuvette loading and removal.

- High reliability, low maintenance

  Innovative "low impact" instrument design and software-driven preventive maintenance improves up-time and reduces maintenance costs.

- Adaptable user interface

  The built-in color touchscreen, process-driven software, and reagent and sample barcode entry adapts to users of different skills and access levels.

- High safety standards

  Built-in safety devices, such as level detection, tube bottom detection, cuvette quality control, and ISE clot detection anticipate potential hazards during operation.

- Flexible sampling

  Eight on-board sample positions accommodate virtually any type of sample carrier, and enable continuous sample placing and removal during operation.

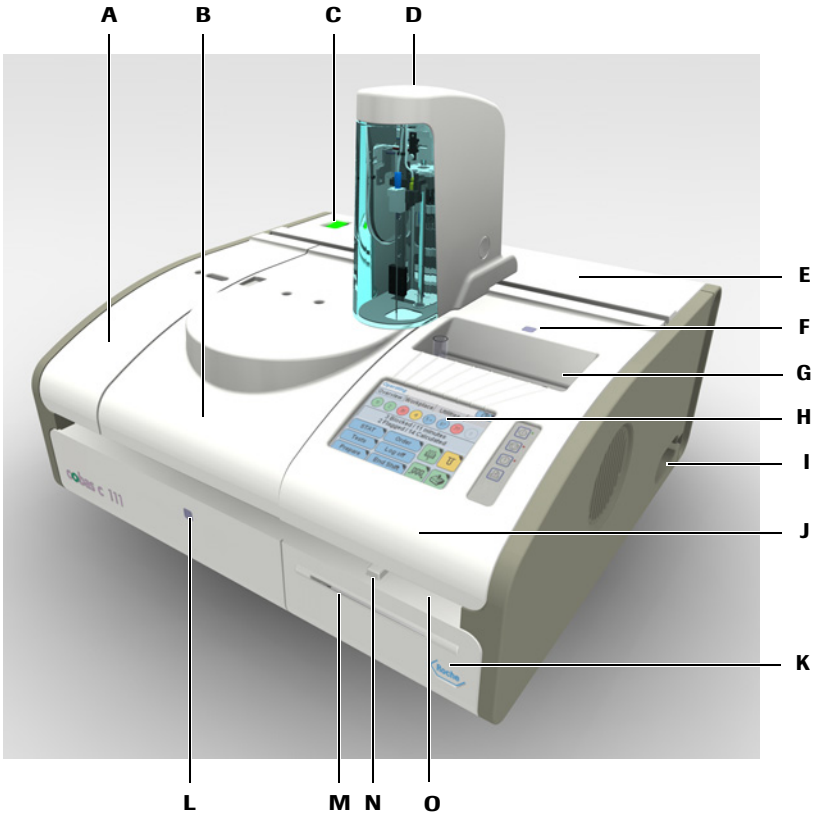
- Data management

  Bidirectional RS-232 and USB ports, on-board thermal printer, and drivers offer the latest in data management capabilities.

Measuring principles

Measurements are performed by means of an absorbance photometer and optionally an ISE (ion selective electrode) module that uses ion selective potentiometry.

A first look at the instrument



A Left service flap (covers wash station, ISE tower, tubing)
B Main cover (covers rotor, reagents, cuvettes, photometer unit)
C Main switch
D Transfer head (holds probe)
E Rear service flap (covers computer boards, power supply, degasser)
F Sample area LED
G Sample area (space for 8 sample tubes)
H Touchscreen
I Fluid connectors
J Right service flap (covers photometer unit, sample area)
K Printer panel
L Main cover LED
M Paper slot
N Release button for printer panel
O USB connector (not shown)

Figure A-2 The **cobas c** 111 instrument

Principles of operation

The **cobas c** 111 main instrument uses absorption photometry for determining the amount of absorbance in a fluid. The absorbance is used to calculate the concentration in the solution.

Loading the sample

The operator identifies the sample, places it on the instrument, and defines the order. (If you work with a host system, the order is defined automatically.)

Measuring process

The measuring process for each test consists of forty regular cycles, each lasting 18 seconds. In each of these cycles, a measurement is taken, irrespective of what other actions take place during this cycle. The application definitions determine what is done in which cycle, and they also define which results are taken into account for the result calculation.

With each cycle, a new test can be started.

The basic process works as follows:

1. Checking the cuvette.

   A measurement is taken to check the quality of the cuvette.

2. Pipetting reagent (R1) to the cuvette.

   After each pipetting action, the system performs a wash cycle to minimize carry-over. During this cycle, the probe and tubing are flushed with water and cleaner.

3. Wait.

   The fluid needs to reach the prescribed temperature. Such a phase can last several cycles.

   During the wait cycles, activities for other tests are performed.

4. Pipetting the next fluid.

   Typically, this would be the sample. The details are defined in the application definitions.

5. Wait.
6. Pipetting the next fluid.
7. Wait.
8. And so on.

Calculating the results

The test result is calculated on the basis of the photometric measurement results. During this process, various checks are performed to ensure that the whole measuring process was technically correct. If values are above or below predefined limits, the test result is flagged.

The results are stored on the system. This includes both the forty measurement results (raw data) and the calculated test result.

Sequence of processing

For a given sample, the tests are processed in the order defined by the time required for their processing (number of cycles), starting with the one that takes the longest. This order can be altered manually by defining a specific process sequence list.

Status of the measuring process

At any stage of the measuring process, the user can check its status on the screen.

Result data management

The system provides storage space for the results of one working day. For backup purposes, the results must be exported to an external storage device once a day.

User interface

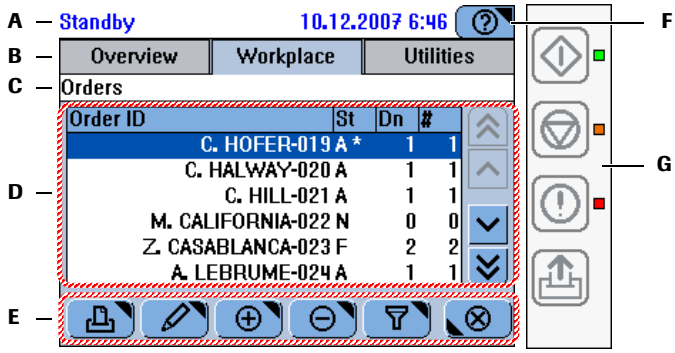
The **cobas c** 111 instrument is equipped with a touchscreen, an on-screen keyboard and four global action buttons. LEDs and acoustic signals let you know when it is safe to add or remove samples, reagents and other fluids.

With buttons and other display items, “traffic light” color coding is used: Green means OK, yellow: watch out, you need to do something, and red means that your intervention is required for processing to continue.

The screens have a clear and consistent layout and are easy to use. The topics are divided in the proven work areas: **Overview** for order and fluid handling, **Workplace** for result handling and details on orders, and **Utilities** for administration tasks.

For details on the user interface, see Chapter 5 *Software*.

The following is an example of a screen. It contains the full range of display items.



A The *status line* displays the system status.

B *Tabs* represent the major work areas.

C The *headline* characterizes the content or function of the screen. If the screen is part of a sequence of screens (wizard), the headline tells you where you are within this sequence.

D The *working area* displays the main content of the screen.

E The *buttons* vary depending on the content of the working area and the screen position within a series of steps (wizard).

F The *Help button* leads to concise information that is relevant to the current screen and situation.

G The *global action buttons* represent the functions that are permanently available: Start, Stop, Alarm, Line Feed. The LEDs next to them point to their status.

Figure A-3 Example of a screen

Wizards

Screens help you perform your tasks. If not all steps of a task can be performed from one screen, the workflow is realized as a sequence of screens, a so-called wizard. **cobas c** 111 wizards do not usually *force* you to perform a task at a certain stage, they just make your work easier.

For details on workflows, see *Workflows and wizards* on page A-74.

When intervention is required

On the screen, there are several methods of telling when your intervention is required:

- *Buttons* and texts are color coded.

	Everything is fine.
	To ensure smooth operation, you need to perform some task.
	The current process or action has not started yet or stopped. You need to do something for it to start or continue.

- *Screens* can contain instructions. For example the text may ask you to place the sample on the sample area or to remove a reagent bottle from the reagent disk.
- *Messages* inform you about the status of current actions.
- A permanent *alarm monitor* alerts you to events you should know about.

Wizards

There are three major wizards: Prepare wizard, Orders wizard, and End Shift wizard. With most tasks that involve more than one step, such as exchanging reagent or other fluid bottles, you are supported by wizards.

Prepare wizard

The Prepare wizard guides you through the tasks that need to be performed at the beginning of a shift. When this wizard is done, the system is ready for processing orders.

Orders wizard

The Orders wizard guides you through the process of creating and changing orders.

End Shift wizard

The End Shift wizard guides you through the tasks that need to be performed at the end of the day or to prepare the instrument for handing over to another operator.

Individual tasks can be performed outside the wizards

Most tasks that make up a workflow can be performed without using a wizard.

If you perform a task independently, you first need to navigate to the appropriate screen and then start the task from there; whereas if you use a wizard, the appropriate screen is displayed automatically.

Using the wizards also ensures that all necessary steps are performed and in the right order.

Daily operation

Overview

Daily operation includes the routine tasks that are required to prepare and monitor the system, and to analyze samples.

When you switch on the system, it performs several checks to make sure that all preconditions are met, for example that all covers are closed or that there are cuvettes available. It then performs self-tests to ensure that all modules function properly.

At the end of the startup phase, the screen is updated to display the current status of the system.

The following table gives an overview of the tasks you might need to perform during daily operation.

	Task	Steps	Navigation	
			With wizard	**As individual steps**
1	Starting the system	1. Switch on the system.		
2	Logging on the system			**Overview** > **Logon**
3	Preparing the system	Start the **Prepare** wizard.	**Overview** > **Prepare**	
		1. Check the external fluid containers.		**Overview** > >
		2. Perform the maintenance actions that are due.		**Utilities** > **Maintenance**
		3. Load the reagent disk.		**Overview** >
		4. Check the reagents.		**Overview** >
		5. Check the cuvettes.		**Overview** >
		6. Perform mixing		**Overview** > > test >
		7. Perform calibrations that are due.		**Workplace** > **Calibrations** > >
4	Defining orders	Start the **Orders** wizard.	**Overview** > **Order** (or **Overview** > **STAT**)	
		1. Identify the sample.		n/a
		2. Select the tests.		n/a
		3. Place the sample.		n/a
		4. Start the run.		
5	Monitoring the progress		n/a	**Overview**
6	Validating results	1. View results.	n/a	**Workplace** > **Result Review**
		2. Handle flagged results.	n/a	**Workplace** > **Result Review** > ... > **Repeat** ... > **Rerun**
		3. Accept results.	n/a	**Workplace** > **Result Review** > > **Accept**

Table A-1 Overview of the daily operation tasks

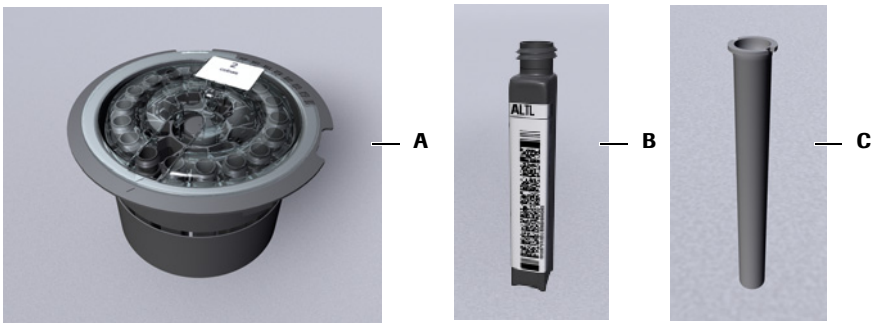
	Task	Steps	Navigation	
			With wizard	As individual steps
7	Performing calibrations			
	Performing individual calibrations	1. Start the wizard.	Workplace > Calibrations > ⊕	
		2. Select the test.		n/a
		3. Prepare and place the calibrators.		n/a
		4. Start the calibration.		◈
		5. Validate the calibration results.		Workplace > Calibrations > ✎
		6. Remove the calibrators.		
	Performing all due calibrations	1. Start the wizard.	Workplace > Calibrations > ⊕	
		2. Select all tests with due calibrations. or Select all tests with calibration due within the forecast period.	🕒 / 🕒	n/a
		3. Prepare and place the calibrators.		n/a
		4. Start the calibration.		◈
		5. Validate the calibration results.		Workplace > Calibrations > ✎
		6. Remove the calibrators.		
8	Performing controls			
	Performing **Default QC**	1. Start the wizard.	Overview > Order > $	
		2. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		3. Start the QC measurement.		◈
		4. Validate the QC results.		Workplace > QC Status > ✎
		5. Remove the controls.		n/a
	Performing an individual QC measurement	1. Start the wizard.	Workplace >	QC Status > ⊕
		2. Select a test.		n/a
		3. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		4. Start the QC measurement.		◈
		5. Validate the QC results.		Workplace > QC Status > ✎
		6. Remove the control.		
	Performing all due QC measurements	1. Start the wizard.	Overview > Order > $ > 🕒	
		2. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		3. Start the QC measurement.		◈
		4. Validate the QC results.		Workplace > QC Status > ✎
		5. Remove the controls.		

Table A-1 Overview of the daily operation tasks

	Task	Steps	Navigation	
			With wizard	**As individual steps**
9	Finishing the shift	1. Check for unfinished orders.		**Workplace** > **Orders** Choose > **Not Finished**
		2. Check for non-validated results.		**Workplace** > **Result Review** Choose > **Not Accepted**
		3. Check for non-transmitted results. (If working with a host system only.)		**Workplace** > **Result Review** Choose > **Not Sent to Host**
		4. Start the **End Shift** wizard.	**Overview** > **End Shift**	
		5. Perform the daily backup.		**Utilities** > **Export** > **Database**
		6. Export the full results.		**Utilities** > **Export** > **Results**
		7. Clean up the database.		**Workplace** > **Orders** > **Workplace** > **Result Review**> **Workplace** > **QC Status** > **Workplace** > **QC History** > **Workplace** > **Calibrations** >
		8. Perform the maintenance actions that are due.		**Utilities** > **Maintenance**
		9. Replace cuvettes.		**Overview** >
		10. Check the external fluid containers.		**Overview** > >
		11. Remove the reagent disk (if last shift).		**Overview** > >
		12. Log off the system.		**Overview** > button with your user name
		13. Switch off the system (if last shift).	n/a	n/a

Table A-1 Overview of the daily operation tasks

Reagent and diluent handling



A Reagent disk
B Reagent bottle with barcode
C Chimney

Figure A-4 Equipment for reagent handling

Reagent disk

On the instrument, the reagents are stored on a reagent disk. It provides space for 27 bottles, allowing up to 14 reagent sets to be installed on the disk, assuming that most tests need two reagents. Extra diluents and cleaners are also loaded on the reagent disk.

You can work with up to eight different reagent disks on one **cobas c** 111 instrument.

You always load and remove bottles while the disk is on the instrument. (The system needs to know exactly what is loaded on the disk.)

When you finished running tests, you can remove the whole reagent disk, place it in a reagent disk container, and store it in a refrigerator.

Bottles

cobas c 111 reagents, diluents and extra cleaners are provided in uniform bottles. They are supplied with two dimensional barcodes and placed on the reagent disk with their cap removed.

Chimneys

Chimneys are bottle inserts that reduce evaporation. For reagents that are especially sensitive to concentration changes, Roche recommend using chimneys on the reagent bottles. (See the package inserts of the tests whether you should use chimneys or not.)

To generally reduce evaporation, you may use chimneys on all reagent bottles.

Reagent set

Up to three reagents can be required to perform a certain test. These reagents are handled in reagent sets. You can define more than one reagent set for a test, but only one can be active.

A reagent set is defined as soon as its first bottle is loaded. From this moment on, whenever you remove or replace a reagent, you do so for all reagents of the set.

Each diluent or cleaner bottle is treated as a separate reagent set.

Volume detection For each reagent set, the number of available tests is continuously calculated.

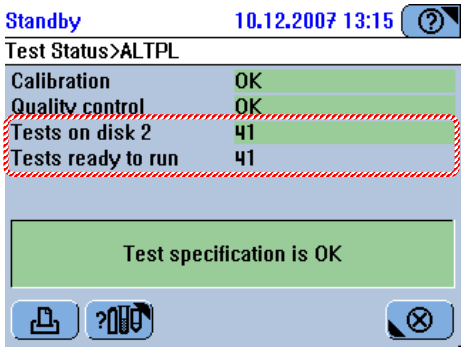


Figure A-5 Remaining tests indication

Periodic mixing Reagents may have a mixing interval defined. This interval is checked by the system every 30 minutes, and mixing is performed without removing the reagent bottles from the reagent disk.

For a reagent set that contains more than one reagent for which mixing is defined, the shortest interval of all reagents of the set is used for all reagents.

Tests are blocked if any reagent they use requires mixing.

Diluents Both, system water and dedicated diluents are used. System water is kept in the external water container, dedicated diluents are supplied in reagent bottles and placed on the reagent disk.

Cleaners Both, a system cleaner and dedicated cleaners can be used. The system cleaner is kept in the external cleaner bottle, dedicated cleaners are supplied in reagent bottles and placed on the reagent disk.

Calibration

Calibration is the process that establishes, under specified conditions, the relationship between values indicated by the analytical instrument and the corresponding known values of an analyte.

Periodic calibration is required because the concentration of reagents can change over time.

Reagents are typically calibrated with a two-point calibration, measuring the predefined value of a multicalibrator and of system water. Some reagents are calibrated using a set of calibrators.

On the **cobas c** 111 instrument, reagents are handled as sets of up to three reagents. (You always load and unload all reagents of a set.) As a consequence, all reagents (bottles) of a set are calibrated when performing calibration.

The system checks when calibration is due.

Each reagent set must have accepted calibration results to be available for use in tests.

When a calibration is due depends mainly on two definitions, the calibration type and the calibration sequence.

Calibration type

The calibration types *Set* and *Lot* define the manner in which the system determines whether there is a valid calibration result for a particular reagent set.

Set calibration Set calibration results are valid for the calibrated set only. They can be generated from any reagent set.

Lot calibration Lot calibration results are valid for the reagent set they were calibrated with and for all subsequent reagent sets of the same lot. Usually, lot calibrations are generated by calibrating the first reagent set of a new lot. There can only be one accepted lot calibration result for the reagents of a given lot.

Let us suppose that you place the first reagent set of a new lot and calibrate it straight away. Let us further assume that subsequent control measurements suggest that a new calibration is required. Within the first 24 hours of placing a set on the system, you can recalibrate it, and possibly existing lot calibration results of this set are superseded. When this period has elapsed you can no longer change the lot calibration results. (To generate new lot calibration results, you would have to delete the existing results and then calibrate a new reagent set.)

Lot calibration is relevant if you work with the calibration sequence [Each Lot and Interval].

The following table illustrates the two calibration types in an example.

Assumptions:

- Sequence: Each Lot and Interval.
- Interval: 5 days.

  (Note that the interval (re)starts when a set is calibrated as a result of the interval expiring or a new lot being started.)

Day	Trigger/Event	Task	Result used	Set	Cal. type	Cal. Usage
1	NA	1. Place first reagent set of new lot. 2. Calibrate set L1/1.	Result 1	L1/1	Lot	Current
2	Reagent empty.	1. Remove set L1/1. 2. Place new set L1/2.	Result 1	L1/2	Set	Current
				L1/1	Lot	-
	Reagent empty.	Replace set whenever it is empty.	Result 1		Set	Current
5	Interval expired.	Calibrate current set L1/n.	Result 2	L1/n	Set	Current
				L1/n-1	Set	Obsolete
6	Reagent empty.	Place new set L1/n+1.	Result 1	L1/n+1	Set	Current
				L1/n	Set	Obsolete
8	Reagent empty. New lot.	1. Remove set L1/n+1. 2. Place new set, which is the first set of a new lot. 3. Calibrate set L2/1.	Result 3	L2/1	Lot	Current
				L1/1	Lot	Obsolete
				L1/n+1	Set	Obsolete
	Reagent empty.	Place new set L2/2.	Result 3	L2/2	Set	Current
				L2/1	Lot	-
10	Interval expired.	Calibrate current set L2/n.	Result 4	L2/n	Set	Current
				L2/n-1	Set	Obsolete
11	Reagent empty.	Place new set L2/n+1.	Result 3	L2/n+1	Set	Current
				L2/n	Set	Obsolete

Table A-2 Example for set change and calibration types

Calibration sequence

The calibration sequence is an application definition. It defines the manner in which the system determines when a calibration is due.

Roche recommend not to change the calibration sequence.

The calibration interval defines the on-board stability of a reagent.

One of the following sequences applies to each reagent set:

No Interval You perform calibration whenever you think fit. Use this value if you are sure that the reagent is stable until it is empty and you replace it with a new one. Calibration is due whenever a new reagent set is loaded on the instrument.

Interval Only You perform calibration only when the interval has expired.

Each Lot and Interval You perform calibration whenever the fist reagent of a new lot is loaded and then each time the interval has expired.

In this case, the interval is related to the date when the lot calibration was generated, and it (re)starts whenever you calibrate a reagent set (as a result of interval expiry or starting a new lot).

You can turn off the interval check by defining its duration as 0 (zero).

Each Set and Interval You perform calibration whenever a new reagent is loaded and when the interval has expired.

The interval starts again whenever you calibrate a reagent set because the interval had expired or a new lot was started.

You can turn off the interval check by defining its duration as 0 (zero).

Calibration status of a set

Each reagent set has one of the following calibration statuses:

CU (current) denotes that the set is on board and that its calibration results are currently used.

OB (obsolete) denotes that the set's calibration results are no longer used.

This status applies for example to the following situations:

- The set was removed and it is empty.
- The set was removed and it is not empty. It was removed more than 30 days ago.

SB (standby) indicates that the set's calibration results are not currently used.

This status applies for example to the following situations:

- A new set was loaded and calibrated while an identical set was still in use (pre-calibration).
- The set was removed not more than 30 days ago and it is not empty.

Calibration result storage

The current and up to five obsolete calibration results are stored on the system. If there are more than five obsolete calibration results, the oldest obsolete calibration results are automatically deleted as part of the daily end of shift activities.

Validating calibration results

Applications define checks for ranges and limits. If these are exceeded, the results are flagged.

Each new calibration result has to be validated. If flags were generated, you must determine their cause and decide whether to accept the result, rerun the calibration or continue using the old calibration results.

You can automatically accept unflagged results and results with flags that are contained in a specific list of flags that should be ignored.

See *Editing the acceptable flags list* on page B-162.

Calibration procedures

There are three basic procedures for performing calibration:

- Calibrating all reagent sets that need calibrating

- Calibrating all reagent sets that will need calibrating during the forecast period

- Calibrating individual reagent sets

Forecast period

The forecast period is a configurable period of time. Calibrations that fall due within this period will be performed collectively.

See *Calibration* on page B-167.

Typically you would set this period to fit your shift length, for example 8 hours. This would enable you to prepare the instrument before the work shift starts and so avoid having to interrupt sample processing for performing calibrations.

Precalibration

At any given time, there is only one accepted calibration result for each test. You can, however, install and precalibrate one reserve reagent set. This is done, for example, to ensure continuous sample processing.

Quality control (QC)

QC is performed at regular intervals to check the integrity of the whole measuring system. For each test, up to three controls are defined. The results are compared against predefined ranges or values and then interpreted accordingly.

Control A control is a sample that has been measured using all tests it is associated with, in order to define the ranges and values that determine the correct functioning of the instrument. This is typically done both for the normal and the pathological analyte concentration.

When QC is due With regards to when it needs to be performed, QC is divided in the following types:

- **QC After Cal**

  The QC measurement is due after calibration of the test.

- Interval QC

  QC is due whenever its interval has expired. QC measurements of this type are performed in a batch, typically once or twice a day.

- **Default QC**

  QC is performed at certain times during routine operation. This is done to fit in with laboratory processes and procedures.

Ways of performing QC With regards to how QC is performed, the following methods are provided:

- **Default QC**

  Default QC is an automated process for performing multiple QC measurements at the time when you define the QC orders. This is the ideal method if you want to perform QC at certain times and days.

  This method only applies to tests whose controls are defined to be performed as part of **Default QC**. Therefore, if you intend to work with the **Default QC** function, you need to configure the tests accordingly.

  Default QC follows a streamlined procedure where the necessary QC orders are automatically defined as soon as you identify a control. An order is defined for each test for which this control is defined, provided the test is currently active on the system. A wizard helps you select the controls, and a placement list supports you in preparing and loading the controls.

- Interval QC

  This method applies to tests whose controls have an interval defined.

  Interval QC is a process that is suitable both for performing a single QC measurement and for performing all QC measurements that are due. You can select all tests that require QC simply by pressing a button. (This selection also reflects QC of the type **QC After Cal**.) A wizard helps you select the controls, and a placement list supports you in preparing and loading them.

Validating QC results

Each new QC result has to be validated. If flags were generated, you must determine their cause and decide whether to accept or ignore the result.

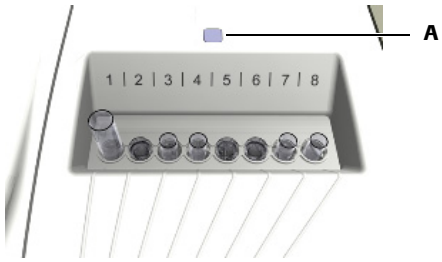
You can automatically accept unflagged results and results with flags that are contained in a specific list of flags that should be ignored.

See *Editing the acceptable flags list* on page B-162.

If you ignore a QC result you exclude the result from further QC result calculations such as QC History statistics.

Sample handling

You can place up to eight sample tubes on the sample area.



A Sample area LED. A green LED indicates that you should place a tube, a blinking yellow LED that you should keep clear of the sample area.

Figure A-6 Sample area with sample tubes

Sample types

The **cobas c** 111 instrument can process the following sample fluids:

- Serum
- Plasma
- Urine
- Whole blood for HbA1c

WARNING

Incorrect results due to inadequate sample preparation

Specimen containing clots may obstruct the probe. Specimen containing bubbles or foam may cause level detection errors and air pipetting. Consequently, incorrect results may be generated.

Take adequate care when preparing the samples.

Incorrect results due to insufficient fluid

Insufficient fluid may lead to inaccurate pipetting and consequently to incorrect results.

Always fill the tubes with enough fluid that at least the defined dead volume of fluid is left when pipetting is complete.

See *Tubes* on page A-54.

Sample tubes

The **cobas c** 111 instrument can use both primary and secondary tubes (cups).

You can use any type of primary tube, as long as their dimensions lay within prescribed limits. Roche recommend using approved cups only.

See *Tubes* on page A-54.

NOTICE

Probe damage due to not removing primary tube caps

The probe is not designed to pierce tube caps. It can get damaged when trying to pierce tube caps.

Always remove the caps of primary tubes before placing them on the instrument.

Sample ID

The sample ID is an identifier of up to 23 alphanumeric characters that is unique within a whole organization, for example the hospital. It identifies the sample and is also used for host communication.

Sample IDs are defined either by scanning a barcode or by typing them manually.

Because there is limited space when displaying lists on screens, Roche recommend to limit the ID to 13 characters.

Sample barcode

You can use sample tubes with or without barcode.

Dilution

Pre-dilution is used when performing calibration.

Post-dilution is used when measuring samples.

(The dilution factor is part of the application definition and therefore does not need to be defined by the operator.)

Removing sample tubes

You can remove sample tubes as soon as pipetting is complete.

Order handling

Order Mode

The order mode reflects the way in which you organize the tests on the test selection screen.

Choose **Easy** if the reagents fit on one or two reagent disks and you work with one test panel on the screen (You can fit up to 25 tests and profiles on this panel).

Choose **Full** if you distribute the reagents across several (up to eight) reagent disks and if you predominantly work with specific groups of tests, for example for emergency situations or for testing diabetes. You can assign up to 20 tests and profiles to each panel (tab).

Order ID

The order ID is an identifier of up to 23 alphanumeric characters that is unique within the laboratory. The order ID identifies the order and links it to the sample.

Order and sample IDs are often identical. Using separate IDs makes sense when working with a host system.

Order IDs are defined either by scanning a barcode or by typing them manually.

Because there is limited space when displaying lists on screens, Roche recommend to limit the ID to 13 characters.

Patient demographics

The **cobas c** 111 software does not support the handling of patient demographic data.

Host connectivity

The **cobas c** 111 instrument can be connected to an external laboratory information system (LIS), a host computer for downloading order information and uploading results, or a **cobas c** 111 Printer Tool.

If the instrument is connected to a host system, the following setups can be configured:

- Downloading order information

  When you identify a sample using the barcode scanner, the appropriate order information is automatically assigned to the order on the system. (The order information was downloaded previously.)

- Performing host queries

  When you identify a sample using the barcode scanner, a query is sent to the host, asking for the order information of the sample in question. This information is then downloaded to the **cobas c** 111 instrument and automatically assigned to the sample on the system.

- Transmitting results

  You can have results automatically transmitted to the host as soon as they are accepted.

For the setup when connecting to a **cobas c** 111 Printer Tool, see the **cobas c** 111 Printer Tool Operator's Manual.

Routine orders

Routine orders are normally defined on the **Overview** tab. The software guides you through the process of assigning the tests to the sample and placing the sample tube on the instrument.

STAT orders

STAT (short turn around time) orders are handled in the same way as routine orders, except that their tests are processed next, irrespective of the scheduling of routine order tests.

Defining orders

There must be at least one free sample tube position when defining an order. You are guided by the software when ordering the tests and placing the samples.

There can be only one order for each test and sample.

Modifying orders

The process for changing an order is similar to that of defining it. You first identify the sample and then change the tests. You can change an order as long as its processing has not yet started.

It is always possible to add a further test to an existing order.

Deleting orders

At the end of a shift, you should delete all orders that are defined on the system. This is to free storage space for the next shift. Deleting the orders is an integral part of the End Shift wizard. (Deleting an order also deletes the corresponding sample results.)

You can export the data to a USB stick and store them on a computer.

Controlling the run

Controlling the execution of test runs is done via the global action buttons.

Press to start the run.

Press to stop the run.

Results

You can check the results on the screen as soon as they are calculated.

Units Results are normally given in your lab units. The units can be configured.

Flags *Result flags* are test-specific. They indicate that the limit of an internal check was exceeded or not reached.

System flags point to the status of the result within the process of analysis; for example, they tell you that the result has not been accepted or that is has not been transmitted to the host successfully.

Printing results You can print all or selected results on the built-in printer.

Validating results All results need to be validated (result accepted, test rerun or repeated).

Result flags help you identify critical results and point to possible actions that need to be taken.

Each test must have accepted calibration results; tests whose associated calibration results are not accepted cannot be performed.

Ratio results The user can manually define ratios. Ratio results are handled like any other sample result, with the exception that they cannot be accepted by the user. They are automatically accepted if all their constituent results are accepted.

Repeating and rerunning tests If a result is flagged, you may decide to run a test again. You can either perform exactly the same test (Repeat) or perform it with a different predefined dilution (Rerun).

Storing results The **cobas c** 111 instrument is designed to hold the sample results of one day's analyzing. Therefore, you need to back up the data regularly to an external medium. (Backing up results is an integral part of the **End Shift** wizard.)

The QC results of the previous and the current months are stored on the system.

Up to five calibration results are stored on the system for each test.

Maintenance

Completing maintenance actions correctly and on time helps to ensure smooth and uninterrupted operation of your instrument.

Maintenance scheduling The **cobas c** 111 instrument facilitates performing the maintenance actions in bundles at the times that suit your laboratory work processes. To that purpose, you can define in the configuration settings one day of the week as your maintenance day.

👁 For information on scheduling maintenance actions, see *Scheduling maintenance actions* on page B-158.

All maintenance actions can be performed any time.

Interval For most maintenance actions a fixed maintenance interval is defined. (You cannot change this interval.) This is the basis upon which the system calculates the date when the actions need to be performed.

The interval timers and counters are reset whenever you confirm that the maintenance action has been performed.

Maintenance actions without predefined intervals are performed whenever necessary, or they are triggered by another maintenance action.

Due date The due date is the last possible maintenance day. This is the date you see when you check the status of maintenance actions.

Ensuring smooth operation Performing all due maintenance actions during the daily **Prepare** or **End Shift** phase ensures that routine operation does not have to be interrupted for performing maintenance actions.

System status

The **cobas c** 111 instrument provides several means of indicating the status of the various parts and processes:

- Color coded LEDs on the instrument inform you when and when not to open covers or place sample tubes.
  See *Color interpretation for LEDs* on page A-122.
- The colors of buttons inform you whether you need to intervene.
  See *Color concept* on page A-74.

  You can check the meaning of a button using the online Help .
- Buttons on the **Overview** tab lead to detailed information on the status of selected processes and hardware items.
- Messages on the screen provide information on individual tasks and events.
- The text in the Status line provides information on the status and activities of the analyzer and photometer unit.

  The following system statuses are defined:

Status	Comment
Standby	The user and host interfaces remain active, as do the reagent cooling system, fluid system, and the cuvette heating.
Maintenance	A maintenance action is being performed. The system is not available for performing tests.
Diagnostics	A diagnostics action is being performed. The system is not available for performing tests.
Operating	Processing is in progress.
Powerup	After switching on, the system performs initialization and functional test.
Powerdown	Regular shutdown is in progress.
E-Stopped	Processing has stopped. User intervention is required to allow the system to resume regular operation.

Table A-3 System statuses

Hardware

The parts and how they work

In this chapter, you will find information on the main hardware components of the **cobas c** 111 instrument.

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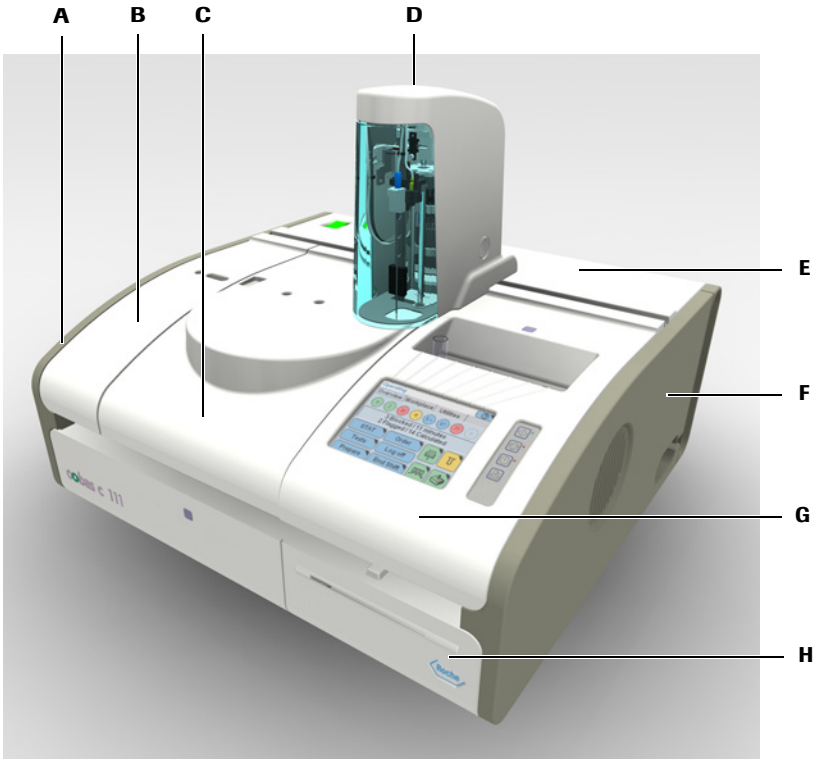
- Printer A-62

Absorbance photometer A-63
Connectors A-64
Fuses A-65
Technical specifications A-66

Covers and panels

The following figure shows the removable panels and the lids that can be opened.



A	Left side panel	**E**	Rear service flap
B	Left service flap	**F**	Right side panel
C	Main cover	**G**	Right service flap
D	Transfer head cover	**H**	Printer panel

Figure A-7 The **cobas c** 111 instrument

Transfer head cover

Provides access to:

- Transfer mechanism
- Probe

Switch off the system before you open this cover.

Left service flap

Provides access to:

- Wash station
- Tubing
- Internal waste tank
- Initialization plate

Open this flap as instructed during maintenance actions, or switch off the system before you remove it.

To open the flap, press its front towards the instrument and lift.

Main cover

Provides access to:

- Rotor
- Reagent disk
- Cuvettes
- Reagent bottles
- Photometer unit

You open this cover whenever you need to handle cuvettes, reagent bottles, or the reagent disk. A green LED indicates that you should place an item, a yellow LED that you should not open the main cover.

To open the cover, press the release button at the underside of the front of the cover.

When you should close the cover an acoustic signal is sounded and the system icon on the System Status screen turns red.

Rear service flap

Provides access to:

- Computer boards
- Power supply
- Transfer unit
- Degasser

This flap should be opened by service representatives only.

Switch off the system before you open this cover and remove the two side panels before opening this flap.

Right side panel

Provides access to:

- Syringe assembly

Remove this panel as instructed during maintenance actions or switch off the system before you remove it.

Right service flap

Provides access to:

- Photometer unit
- Sample area
- Touchscreen
- Data management computer

Open this panel as instructed during maintenance actions or switch off the system before you open it.

Printer panel

Provides access to:

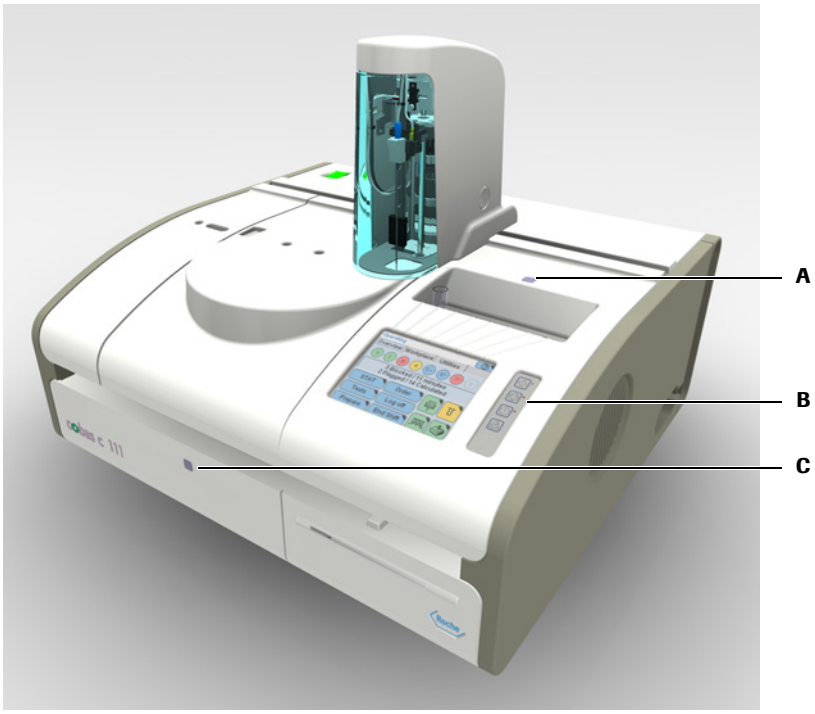
- Printer paper.

You can open this flap any time as long as the printer is not printing.

To open the panel, press the release button.

LEDs

LEDs are placed on key positions on the **cobas c** 111 instrument. They inform you whether you can perform certain actions.



A Sample area LED
B Global button LEDs (from top: Start LED, Stop LED, Alarm LED)
C Main cover LED

Figure A-8 The **cobas c** 111 instrument

Interpreting the LED colors

LED	Color	Meaning
Main cover LED	Off	No activities in this area. You can open the main cover.
		User intervention is required, for example you are expected to place or remove a bottle.
		The system is performing some action. Do not handle the cover.
	An acoustic signal is sounded when the cover is open while the system is in **Operating** state. You can adjust the volume (**Utilities** > **Configuration** > **System** > **Volume**).	
Sample area LED	Off	No activities in this area. You can remove sample tubes.
		You are expected to place a sample tube.
	Blinking	The transfer head is approaching. Do not place your hand or any object in the sample area.
Start LED	Off	You cannot start the measuring process.
		You can start the measuring process.

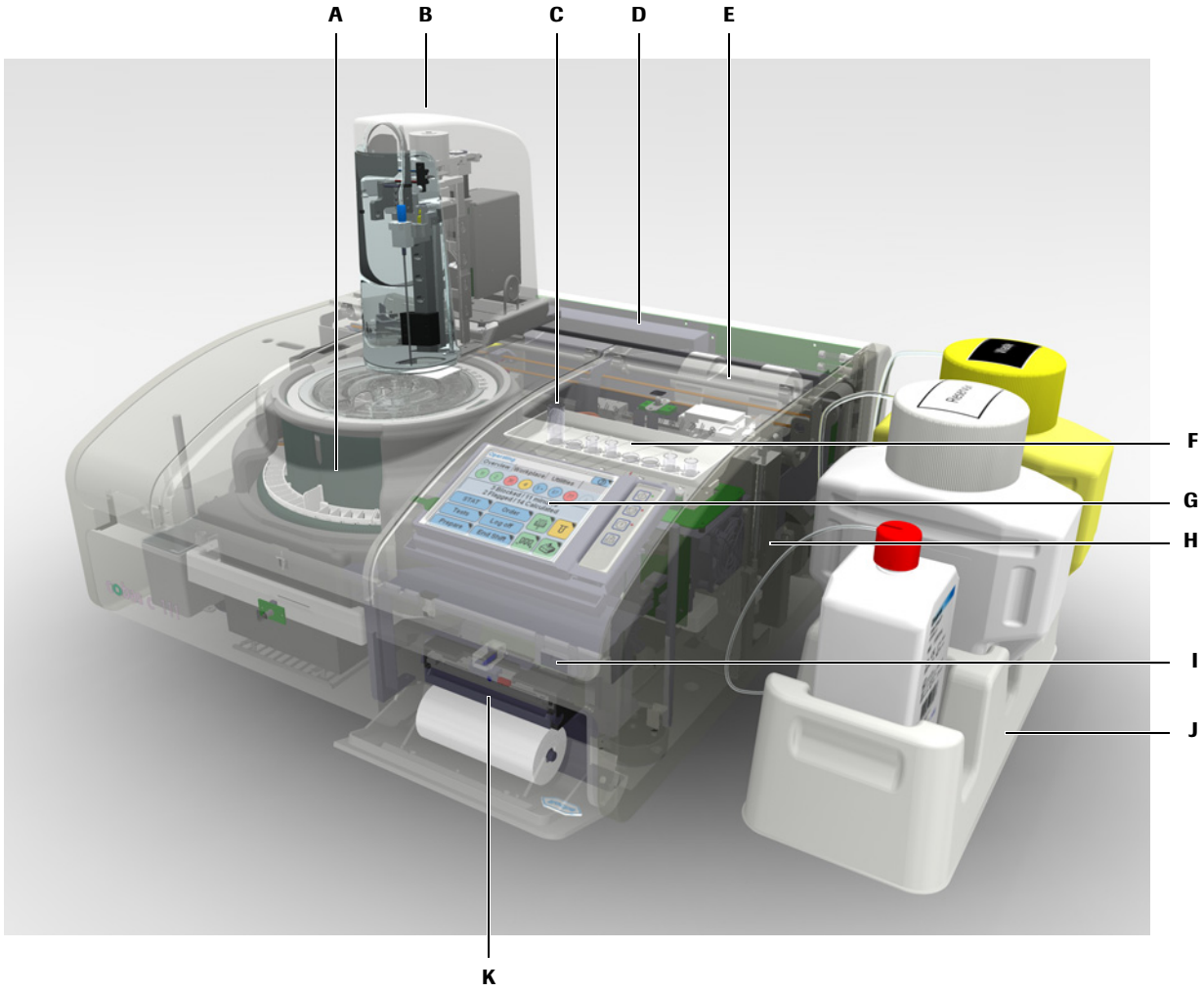
Table A-4 LEDs and their meaning

LED	Color	Meaning
Stop LED	Off	Pressing ⊘ does not have any effect.
		Pressing ⊘ leads to the various stop options.
Alarm LED	Off	There are no unconfirmed alarm messages.
		There is at least one unconfirmed alarm message. You need to deal with it as soon as possible.
		There is at least one unconfirmed alarm message. You need to deal with it immediately, processing may not be able to continue unless you do so.
	An acoustic signal is sounded when an alarm is generated. You can adjust the volume (**Utilities** > **Configuration** > **System** > **Volume**).	

Table A-4 LEDs and their meaning

Main components

The following figure illustrates the main components of the **cobas c** 111 instrument.



A	Rotor	**E**	Degasser	**I**	Front USB port
B	Transfer unit	**F**	Sample area	**J**	External fluid rack
C	Photometer unit	**G**	Display	**K**	Printer
D	PCB main board	**H**	Syringe assembly		

Figure A-9 Main hardware components

Rotor Provides a cooled area for reagents (cooling assembly) and a heated channel for cuvettes. It moves the containers to the correct position for loading, removal, pipetting, and measuring.

Transfer unit Pipettes sample, reagent, and other fluids from their source to target containers such as cuvettes or the wash station.

Photometer unit Contains the absorbance photometer used for making absorbance measurements.

PCB main board Controls the instrument hardware.

Fluid system (not shown) Transports all fluids around the instrument, including sample, reagent, calibrator, control, diluent, cleaner, system water, and waste.

Syringe assembly Performs the aspiration and dispensing of fluids. This includes the supply of water and cleaner to clean the probes in the wash station after every pipetting action, which prevents carry-over between tests.

Degasser Removes possible air bubbles from the system water.

Sample area Eight positions for holding sample tubes. This area is also used for placing calibrators, controls, and auxiliary fluids.

Display The touchscreen provides the user interface for controlling and managing the **cobas c** 111 instrument.

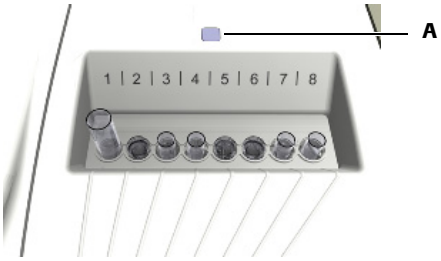
Front USB port This port is used for the USB stick when backing up data or loading data on the system.

Hardware overview

Sample area

The sample area provides eight positions for placing sample tubes. You can place primary and secondary tubes.

See *Tubes* on page A-54.



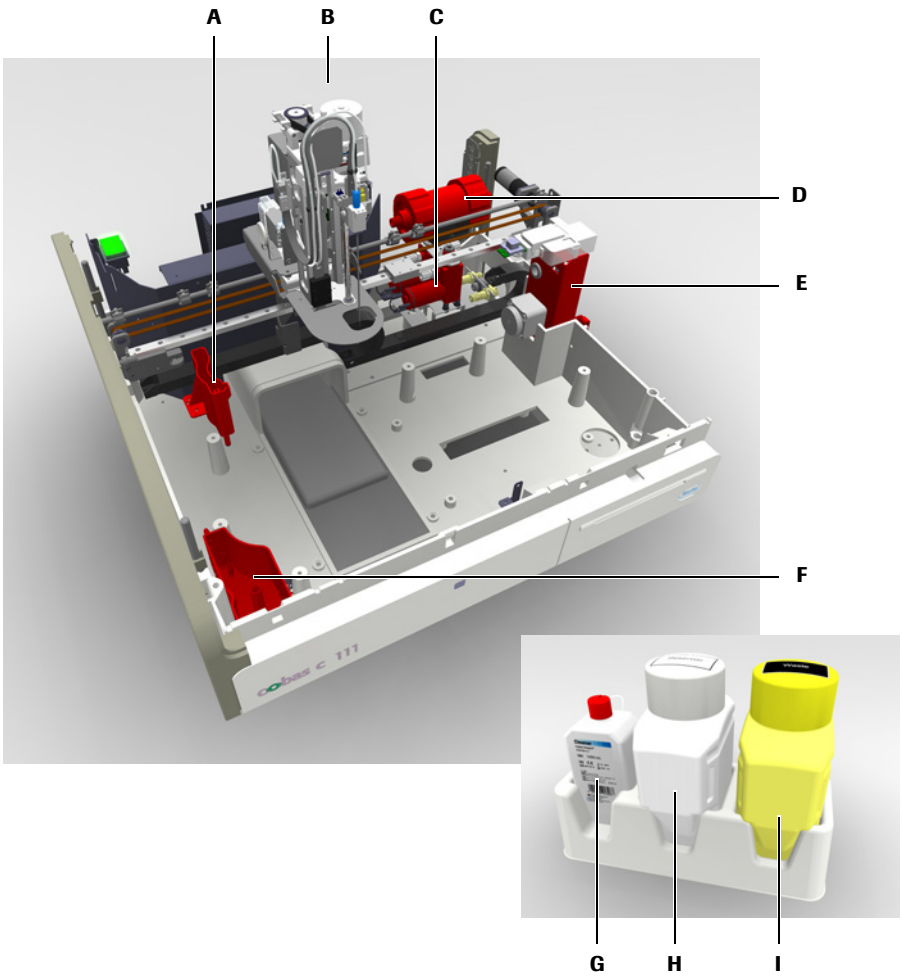
A The LED indicates that the transfer tower is approaching or that you should place a sample tube.

Figure A-10 Sample area with sample tubes

Place the samples when instructed by the system to do so. For calibrators, the system tells you on which position to place them, with the other fluids, you can choose any free position.

Fluid system

The fluid system consists of all the valves, pumps, tubing, syringe, fluid sensors, water and waste containers, the wash station, and the probe. It transports all fluids around the instrument, including sample, reagent, calibrator, control, diluent, cleaner, system water, and waste. The fluid system also delivers the correct amounts of fluids to the cuvettes.



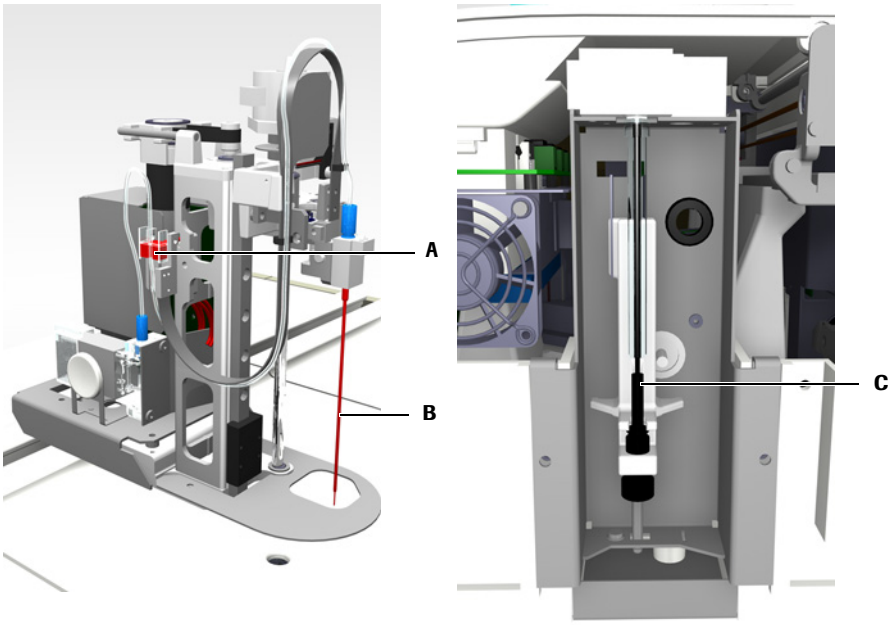
A Wash station
B Transfer head (with probe)
C Pumps
D Degasser
E Syringe assembly
F Internal waste tank
G Cleaner bottle (red cap)
H Water container (white)
I Waste container (yellow)

Figure A-11 Fluid system

NOTICE

To prevent overflow of the internal waste tank when the system is in Standby status, the waste is periodically pumped to the external waste container. (Condensation can build up in the cooling assembly while the system is in **Standby** status.)

Probe and syringe



A Fluid sensor
B Probe
C Syringe

Figure A-12 Probe and syringe

The probe is connected by tubing to:

- The syringe to ensure the pipetting of the required amounts of fluid.
- The external water container and cleaner bottle to ensure supply of fresh water and cleaner.

See maintenance action *Clean the probe manually* on page C-12.
See maintenance action *Deproteinize the probe* on page C-10.
See *Replacing the probe* on page B-125.

Syringe assembly

The syringe assembly controls the aspiration and dispensing of fluids. It also controls the supply of water and cleaner to clean the probes in the wash station after every pipetting action, which prevents carry-over between tests.

Wash station

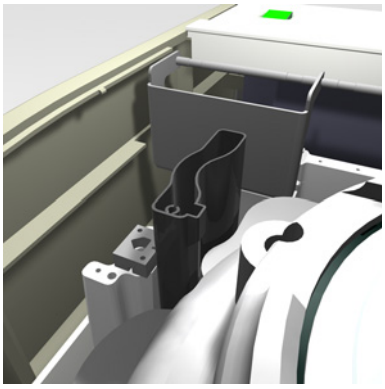


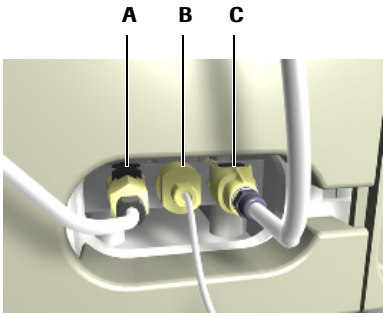
Figure A-13 Wash station

The probe is washed after each pipetting. It is lowered in the wash station and then cleaner is pumped through the probe to wash it in and outside. Next water is pumped through the probe to flush away the cleaner.

The wash station is connected by tubing to the internal waste container.

External fluid connectors

The three external fluid containers must be properly connected before you switch on the **cobas c** 111 instrument.



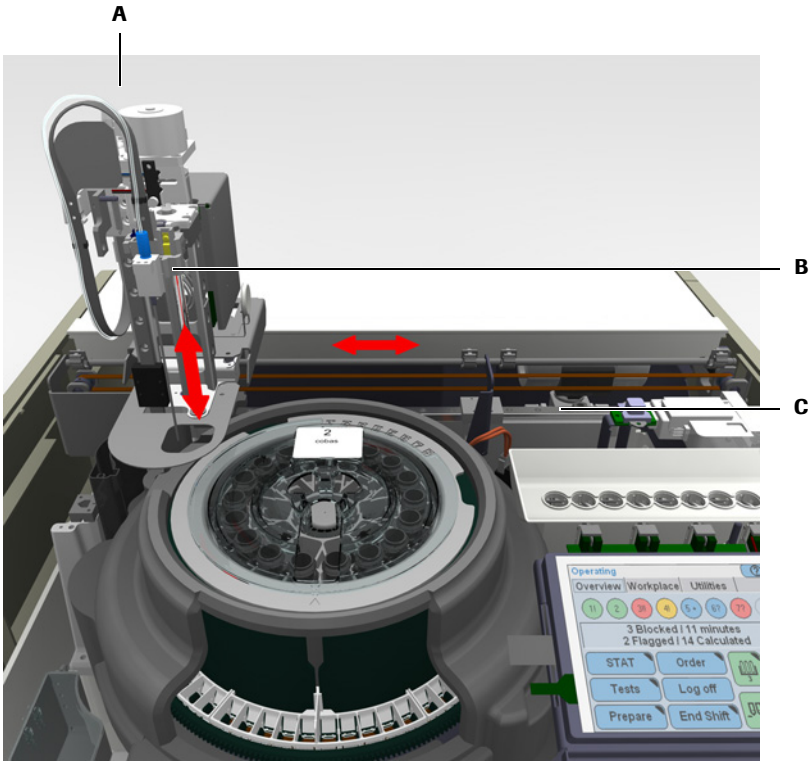
A Water connector
B Cleaner connector
C Waste connector

Figure A-14 External fluid connectors

Transfer unit

The transfer unit moves the probe to the correct positions for all pipetting and cleaning actions.

The following figure shows the major parts of the transfer unit.

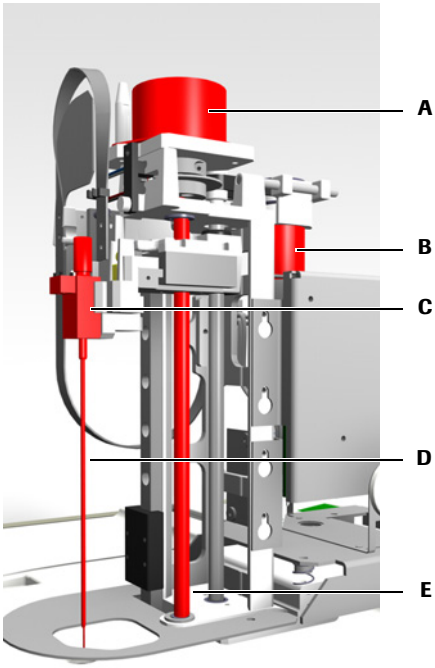


A Transfer head
B Probe holder carriage
C Transfer X guide rail

Figure A-15 Major elements of the robotic transfer unit

Transfer head The transfer head moves horizontally (along the X-axis); the probe moves up and down (Z-axis), and it performs a rotational movement for mixing the cuvette and reagent bottle content.

Transfer head arrest When the transfer head is obstructed in its horizontal movement, it immediately stops. All pipetting and processing actions stop.



A Mixing motor
B Transfer Z motor
C Probe holder
D Probe
E Mixer movement axis

Figure A-16 Transfer head

Mixing motor The mixing motor is mounted on the carriage. When running, it generates a circular movement of the probe. This movement is used for mixing the content of cuvettes and reagent bottles.

Probe The probe has a flat tip. This is required for tube bottom detection. Because such a probe cannot pierce a bottle cap, all bottles must be placed on the instrument with their caps removed.

Level detection A sensor detects when the probe enters a fluid. On the basis of this level, the system establishes whether there is enough fluid to perform the scheduled pipetting action.

Tube Bottom detection A physical sensor is activated as soon as the probe touches the bottom of a sample tube.

This mechanism also works when the probe touches an object outside the tube. In both cases, probe action stops and an appropriate alarm message is generated.

Fluid containers

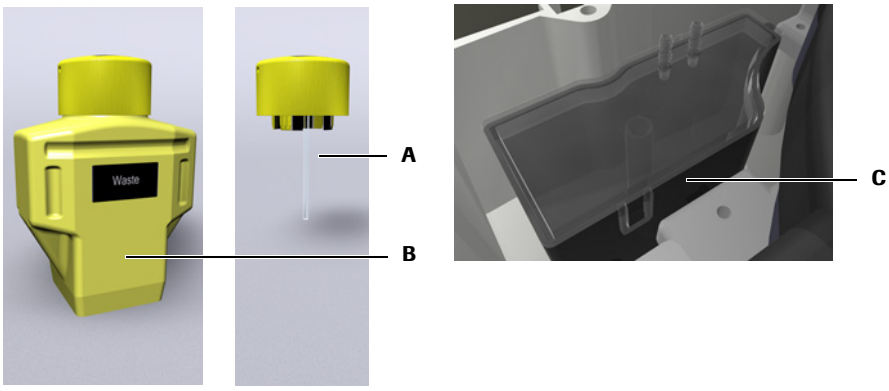
The following table shows which container is used for which fluid:

Fluid	Container(s)	Position
Sample	Tube	Sample area
Control	Tube	Sample area
Calibrator	Tube	Sample area
Diluent	Reagent bottle	Reagent disk
System cleaner	External cleaner bottle	External fluid rack
Cleaner	Reagent bottle	Reagent disk
Reagent	Reagent bottle	Reagent disk
Water	Bottle	External fluid rack
Waste	Bottle	External fluid rack

Table A-5 Fluid containers, what they are used for and where

The term tube includes all kinds of tubes, as long as their dimensions lay within prescribed limits. It also includes secondary tubes (cups). See *Tubes* on page A-54.

Waste containers



A Tubing adapter
B External waste container
C Internal waste tank

Figure A-17 Waste container

Internal waste tank

The internal waste tank collects the waste from the wash station and the ISE unit, if this is used. It also collects the condensation from the cooling assembly in the rotor.

The internal waste tank is connected by tubing to:

- External waste container
- Wash station
- Reagent cooler (condensation)
- ISE unit (if installed)

External waste container

The yellow external waste container is placed on the external fluid rack. It is designed to be washed and reused.

Because the system periodically performs wash actions, an external waste container must be connected at all times. Therefore, when you empty the waste container, you immediately replace it with the spare container and then empty the original container. (The instrument is supplied with a spare waste container.)

There is no active level monitoring for the external waste container, but you are notified if the external waste container has not been emptied for more than one day.

The external waste container is connected by tubing to the internal waste tank.

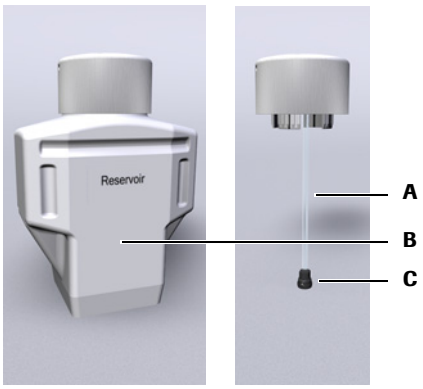
See *Connecting and disconnecting the external fluid containers* on page B-127.
See *Checking the status of the external fluid containers* on page B-15.
See maintenance action *Clean the water and waste containers* on page C-16.

Water container

The white water container is positioned on the external fluid rack. Attached to the cap is a suction tube, which is equipped with a water filter.

There is no active level monitoring for the water container, but you are notified if the water container has not been refilled for more than one day.

The water container is designed to be washed and refilled.



A Tubing
B Container
C Water inlet filter

Figure A-18 Water container

The water container is connected by tubing to:

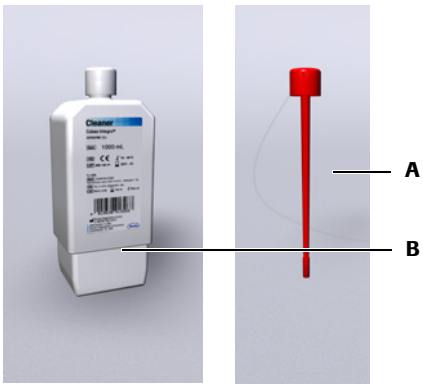
- Wash pump
- Syringe assembly
- Probe

See *Connecting and disconnecting the external fluid containers* on page B-127.
See *Checking the status of the external fluid containers* on page B-15.
See maintenance action *Clean the water and waste containers* on page C-16.
See maintenance action *Replace water inlet filter* on page C-19.

Cleaner bottle

The cleaner bottle is positioned on the external fluid rack. It is designed to be replaced when empty.

Level monitoring for the cleaner bottle is based on the number of cleaning and pipetting actions that were performed.



A Tubing adapter **B** Cleaner bottle

Figure A-19 Cleaner bottle

When delivered, the bottle has a white cap. During installation, this is replaced by a red cap with tubing attached to it (tubing adapter).

The cleaner bottle is connected by tubing to:

- Syringe assembly
- Probe

See *Connecting and disconnecting the external fluid containers* on page B-127.
See *Checking the status of the external fluid containers* on page B-15.

Reagent bottles

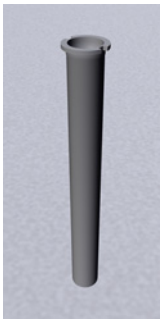
The **cobas c** 111 instrument works exclusively with reagent bottles that are equipped with a two-dimensional barcode.

Each bottle holds up to 20 mL of fluid. The actual volume depends on the test.

Place the bottles on the reagent disk as instructed by the software.

Reagents are handled in reagent sets. A set consists of up to three reagents. You always load and replace all bottles of a set.

Chimneys



Chimneys are bottle inserts that reduce evaporation.

For reagents that are especially sensitive to concentration changes, Roche recommend using chimneys on the reagent bottles. (See the package inserts of the tests whether you should use chimneys or not.)

To generally reduce evaporation, you may use chimneys on all reagent bottles.

WARNING

Incorrect results due to declining reagent quality

If the application definitions (see package insert) recommend the use of chimneys, the corresponding calibration intervals apply to conditions when working with chimneys.

Roche recommend using chimneys whenever this is recommended on the test insert.

Tubes

The **cobas c** 111 instrument can use both primary and secondary tubes (cups).

You can use any type of primary tube, as long as their dimensions lay within prescribed limits.

- Maximum height (including secondary tube): 102 mm
- Minimum height: 70 mm
- Maximum outside width: 16.3 mm
- Minimum outside width: 11.8 mm

WARNING

Incorrect results due to insufficient fluid

Insufficient fluid may lead to inaccurate pipetting and consequently to incorrect results.

Always fill the tubes with sufficient fluid that at the end of the pipetting process at least the dead volume of fluid is left.

See *Tubes* on page A-54.

Incorrect results due to inappropriate tube and cup placement

Inappropriate tube and cup placement may lead to inaccurate pipetting and consequently to incorrect results.

Make sure that the primary tubes are placed centrally and perfectly vertically in the holders in the sample area and that they are inserted firmly.

Make sure that secondary tubes are placed centrally on the primary tubes and that they rest fully on them.

NOTICE

Probe damage due to not removing primary tube caps

The probe is not designed to pierce tube caps. It can get damaged when trying to pierce tube caps.

Always remove the caps of primary tubes before placing them on the instrument.

The following table lists a few typical tubes that are suitable, and it gives the dead volume for each of them.

Tube name	Dead volume
13 x 75 mm	500 µL
13 x 100 mm	500 µL
16 x 75 mm	700 µL
16 x 100 mm	700 µL

Table A-6 Typical examples of suitable tubes

Roche recommend using approved cups only. The following table lists the approved cups.

Cup name	Dead volume	Placement
Hitachi standard cup	75 µL for 2 µL sample volume	Directly on sample area
Hitachi micro cup	50 µL for 2 µL sample volume	Directly on sample area
Roche Diagnostics Standard false bottom tube	75 µL for 2 µL sample volume	Directly on sample area

Table A-7 Typical examples of suitable tubes

The Hitachi standard and micro cups can be placed on top of 16 x 75 mm tubes.

Cups with a rim can be placed directly on the sample area, whereas cups without rim must be placed on top of primary tubes.

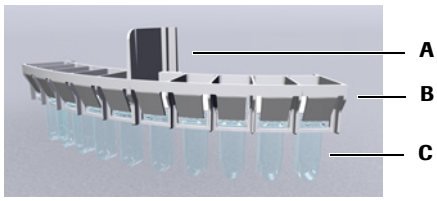
Cuvettes

All optical measurements are made using the same transparent plastic containers, called cuvettes. Samples are automatically transferred from a sample tube to the cuvettes on the cuvette ring.

Cuvettes are disposable to eliminate carry-over.

Cuvette segments

Each segment holds 10 cuvettes.



A Segment handle
B Cuvette segment holding individual cuvettes
C Cuvettes

Figure A-20 Cuvette segment

Handling cuvettes

Cuvettes are supplied in boxes containing cuvette sets. Each set contains a number of cuvette segments. This way, the cuvettes can easily be handled without touching them.

Loading and removing cuvettes is guided by the system software. When handling is required, the rotor moves the cuvette segments to the cuvette port, where you can load or remove them. You handle one segment at a time. Cuvette segments are placed in the cuvette ring of the rotor.

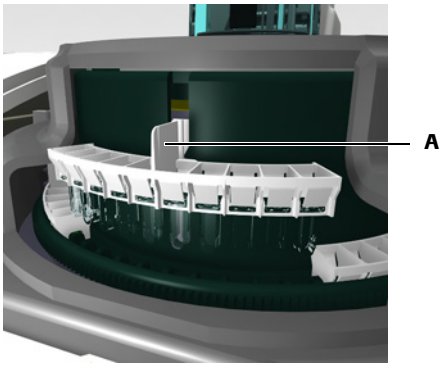
See *Preparing cuvettes* on page B-28.

WARNING

Incorrect results due to scratched or soiled cuvettes

Scratches and impurities on the cuvettes distort the measurements.

Do not touch the cuvettes and make sure they do not touch other items when handling them.



A Hold the segment by its handle. Make sure not to touch the cuvettes.

Figure A-21 Handling a cuvette segment

Reagent handling

Loading and removing reagents is guided by the system software. When handling is required, the rotor moves the bottles to the reagent port, where you can load or remove them. You handle one reagent bottle at a time. Reagent bottles are placed on the reagent disk.

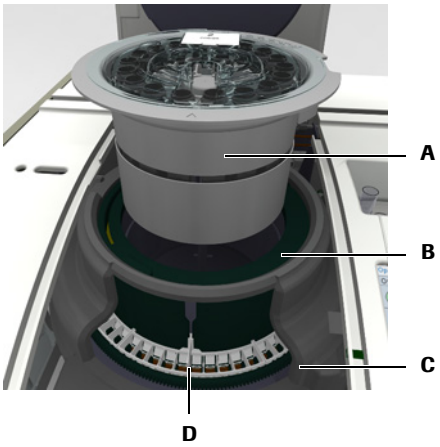
See *Preparing the reagents* on page B-22.

Figure A-22 Handling a reagent bottle

Rotor

The rotor provides the following features:

- Space for up to 27 reagent bottles (on the reagent disk)
- Space for up to 60 cuvettes (in the cuvette ring)
- A cooled environment for reagents (reagent cooler)
- A temperature controlled environment for samples (cuvette ring)
- A synchronized transport mechanism to move reagent bottles and cuvettes to the pipetting, loading, and measuring positions.

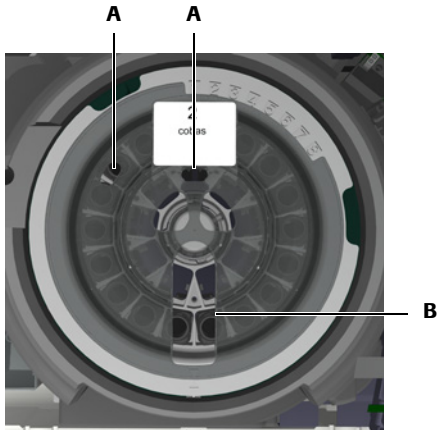


A Reagent disk
B Reagent cooler
C Temperature controlled cuvette ring (not visible)
D Cuvette segment

Figure A-23 Main rotor elements

Rotational movement

The bottles and cuvettes are positioned in a manner that they can be moved to the various positions by a rotational movement. There are positions for loading and removal (reagent and cuvette ports), pipetting, and measuring.



A Pipetting positions
B Reagent port

Figure A-24 Reagent port on the reagent disk

Reagent disk

The reagent disk holds up to 27 reagent bottles. It is designed to be handled as one unit, including the bottles. When not used on the instrument, the reagent disk is placed in a container and stored in a refrigerated place.

Figure A-25 Reagent disk

NOTICE

Damage to the reagent disk

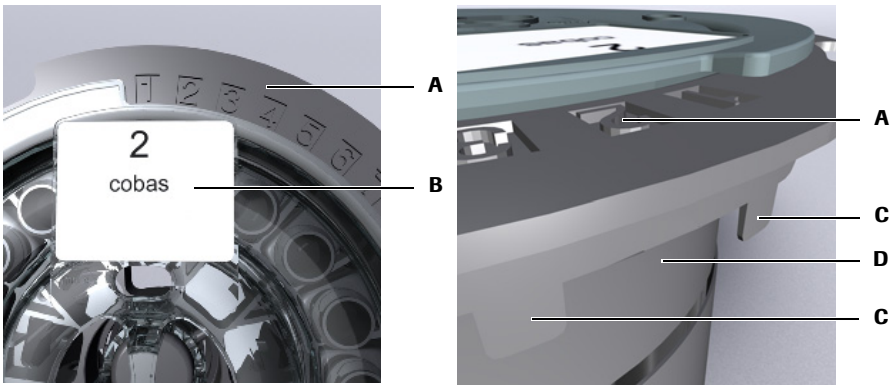
The reagent disk is designed to handle reagents while it is loaded on the instrument. The cover is equipped with a locking mechanism.

Always remove and load reagents while the reagent disk is on the instrument and by using the software supported procedures.

See *Preparing the reagent disk* on page B-21.

Reagent disk ID

You can use up to eight different reagent disks on one **cobas c** 111 instrument. Each reagent disk is equipped with numbered tabs. For automatic disk identification by the instrument, one—and only one—of these tabs is removed. The number of this removed tab is the disk ID. When you label the disk, make sure that the number on the label corresponds to that of the removed tab.



A Reagent disk IDs. There are eight possible IDs.

B Disk label. The number must correspond to the reagent disk ID.

C Identification tabs

D The tab has been removed for automatic disk recognition

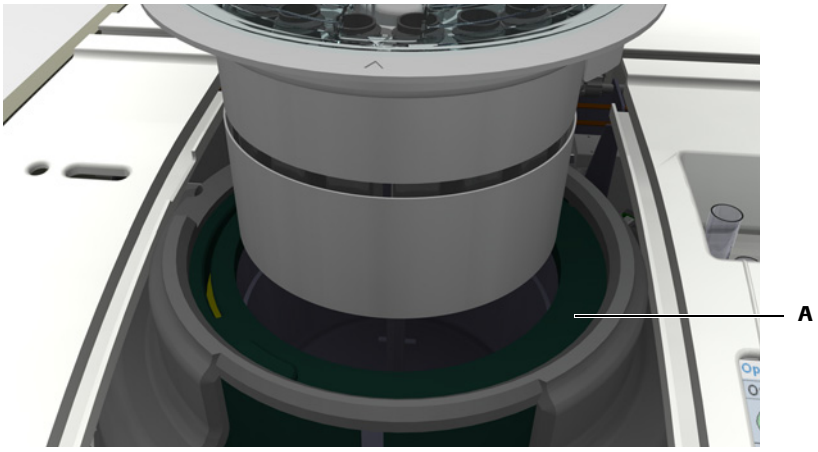
Figure A-26 Reagent disk ID

Reagent disk container

For storage outside the instrument, the reagent disk is placed in a container. This reduces evaporation of reagents and prevents their contamination.

Reagent cooler

The reagent cooler holds the reagent disk with its reagent bottles. The temperature in the cooler is kept within the range of 6 to 10°C.



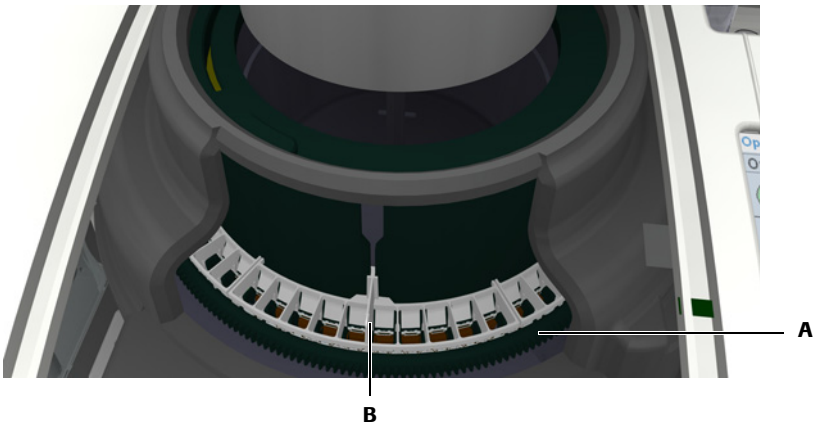
A Reagent cooler

Figure A-27 Reagent cooler

See maintenance action *Clean reagent disk and sample area* on page C-14.

Cuvette ring

The cuvette ring holds up to 6 cuvette segments, each containing 10 cuvettes.



A Cuvette ring **B** Cuvette segment

Figure A-28 Cuvette ring

Cuvettes fit neatly in the cuvette ring, without touching the walls when being moved along the ring.

See *Preparing the reagents* on page B-22.
See maintenance action *Clean reagent disk and sample area* on page C-14.

Barcode scanner

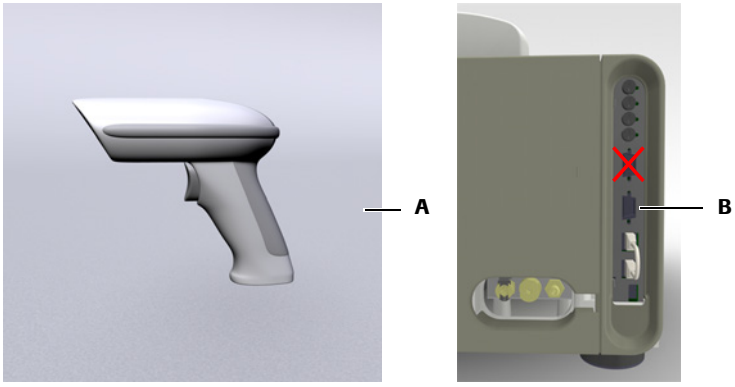
A hand-held barcode scanner is used for reading barcoded labels.

WARNING

Loss of sight

The intense light of the LEDs may severely damage you eyes. Do not stare into the LEDs.

Scanning equipment using LED technology is covered by the international standard IEC 60825-1 LED Safety: Class 1.



A Barcode scanner **B** Scanner connector on the instrument

Figure A-29 Hand-held barcode scanner

Connect to the lower COM2 port

Always connect the barcode scanner to the lower of the two serial communication connectors (B).

For information on how to use the barcode scanner, see *Using the barcode scanner* on page B-89.

The following containers are always supplied with barcodes:

- Reagent bottles
- Diluent bottles
- Auxiliary fluids (diluents, cleaners etc.)

Sample tubes can be used with or without barcoded labels.

Reagent bottle barcode

On the reagent bottles, barcode of the PDF417 format is used.

The barcode contains the following information:

- Part ID
- Lot number
- Expiration date
- Reagent volume
- Serial number of bottle
- Test data

Sample barcode

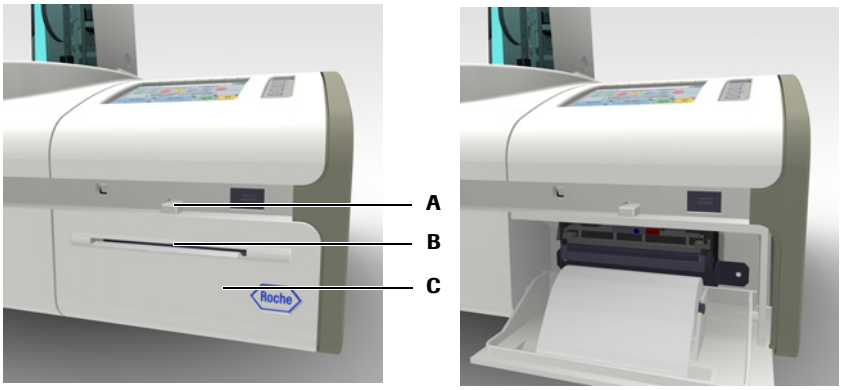
The following barcode types are supported for sample tube identification:

- Codabar
- Codabar 2 of 7
- Code 3 of 9
- Code 128
- EAN
- Interleaved 2 of 5
- UPC (A, E)

A sample barcode must include a checksum at the end.

Printer

The **cobas c** 111 instrument has a built-in thermal printer with a 112 mm paper roll. The printer is used for example for printing placement lists, results, maintenance action instructions, and status information on various items such as the loaded tests.



A Panel release button
B Paper slot
C Printer panel

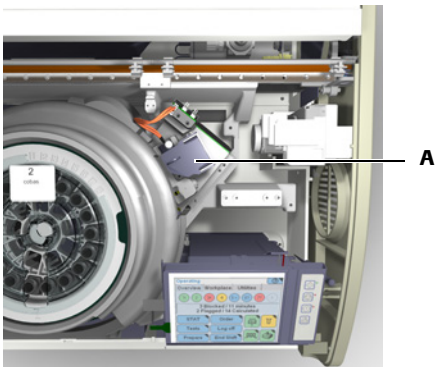
Figure A-30 Printer

See maintenance action *Refilling printer paper* on page B-122.
See *To clear the paper jam* on page D-46.

Absorbance photometer

The **cobas c** 111 main instrument uses the absorbance photometry measuring method.

Absorbance photometer



A Photometer unit

Figure A-31 Photometer unit

The measurements are taken without removing the cuvette from the rotor.

Halogen lamp

The Halogen lamp is mounted on a holder for easy replacement. The system informs you when you need to replace the lamp.

See maintenance action *Replace photometer lamp* on page C-24.

Wavelengths for the absorbance photometer

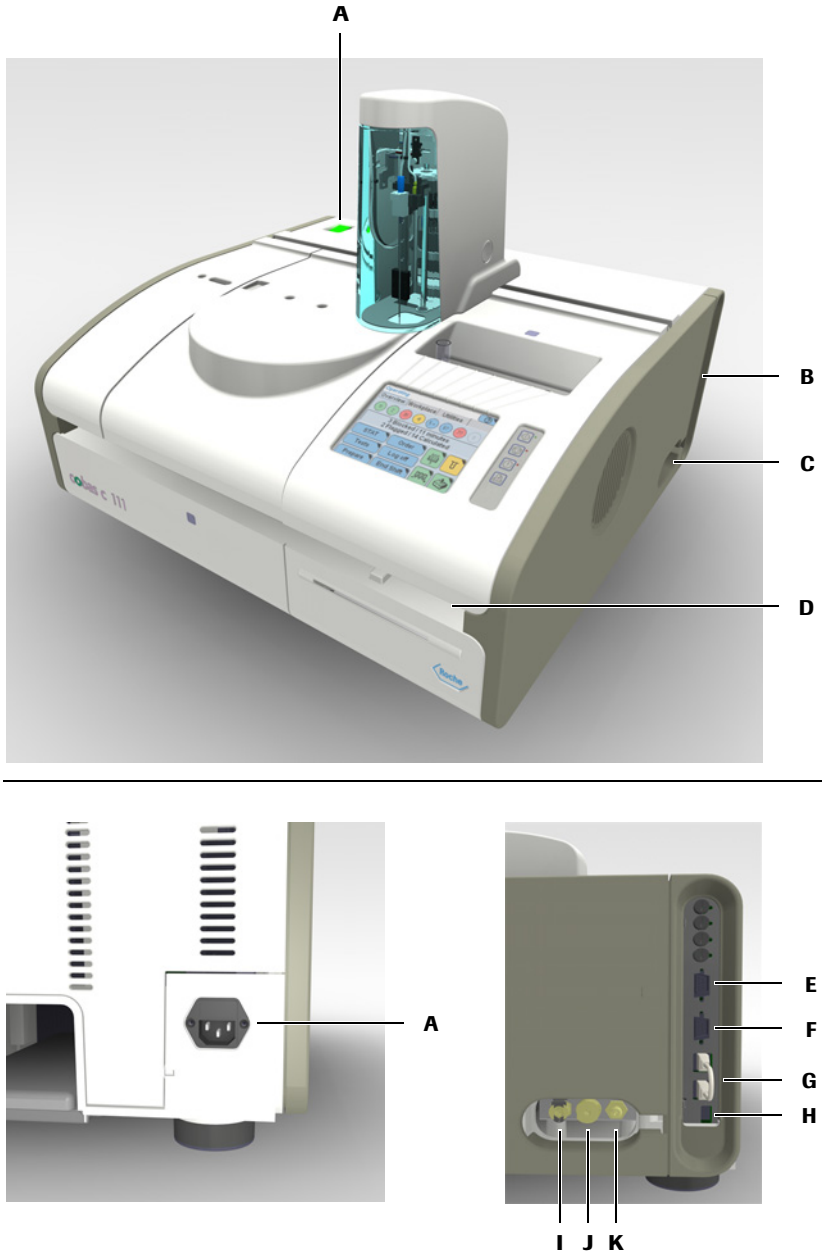
For each cuvette, the absorbance photometer measures light intensity at 12 different wavelengths:

340 nm	449 nm	520 nm	629 nm
378 nm	480 nm	552 nm	652 nm
409 nm	512 nm	583 nm	659 nm

Measurement principles

See *Principles of operation* on page A-19.

Connectors



A Power supply
B Data and communication connectors
C Fluid connectors
D Front USB port (not shown)
E Serial communication connector
F Barcode scanner connector
G Maintenance connectors (Do not remove the cable.)
H USB 2 connector (for troubleshooting)
I Water connector
J Cleaner connector
K Waste connector

Figure A-32 Connectors

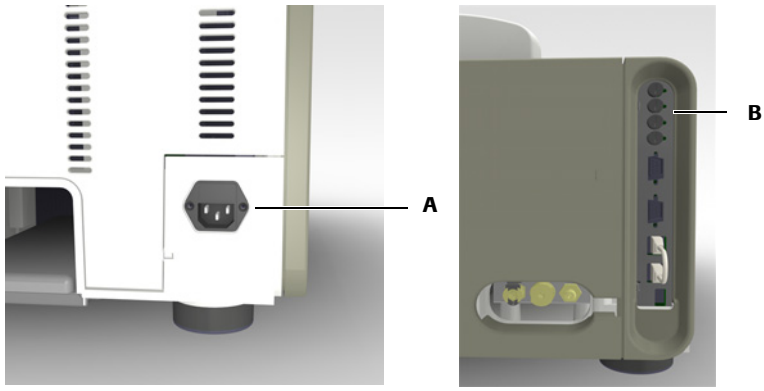
Fuses

WARNING

Electrical shock by electronic equipment

Do not attempt to work in any electronic compartment. Installation, service, and repair must only be performed by authorized and qualified personnel.

The mains fuses are situated at the rear of the instrument, above the power connector; the internal fuses are situated on the right side of the instrument, at the top of the connector panel.



A Power connector with T6.3 A H 250 V fuse

B Low voltage fuses (T3.15 A)
F1: Heating system
F2: Motors
F3: Cooling assembly
F4: Photometer unit and LEDs

Figure A-33 Fuses

See *To change the mains fuses* on page D-47.
See *To change a low voltage fuse* on page D-49.

Technical specifications

NOTICE

Every effort has been made to ensure that all the information contained in these specifications is correct at the time of printing. However, Roche Diagnostics reserves the right to make any changes necessary without notice as part of ongoing product development.

Physical dimension

Width (with ISE unit)	590 mm (720 mm)
Depth (with ISE unit)	550 mm (550 mm)
Height (with ISE unit)	480 mm (480 mm)
Weight (with ISE unit)	Approximately 32 kg (35 kg)

Power requirements

Line voltage	100-125 V and 200-240 V (-15%, +10%)
Line frequency	50 Hz (±5%) and 60 Hz (±5%)
Power consumption	250 VA
Insulation coordination	Installation category II (IEC 61010-1)
Main fuse	T6. 3 A H 250 V
Low voltage fuses	T3. 15 A L 250 V
Battery	Lithium 3.6 V 2.3 Ah SL-360/S

Power requirements ISE unit (optional unit)

Line voltage	100-240 V (±10%)
Line frequency	50 Hz (±5%) and 60 Hz (±5%)
Supply voltage	19-24 V DC, Min. 2A
Power consumption	70 VA
Insulation coordination	Installation category II (IEC 61010-1)

Measurement principles

Absorbance photometry	(enzymes, substrates, drugs of abuse)
Potentiometry	ISE (ion selective electrodes) Na^+, K^+, Cl^-

Environmental conditions

Temperature	Running conditions: 15-32°C
	Transport and storage: -25 to +60°C
Humidity	Running conditions: 30-80% at 15-32°C, non condensing.
	Transport and storage: 10-95%, non condensing
Pollution	Degree 2 (IEC 61010-1)
Altitude	Max. 2000 m above sea level

Throughput

Photometric	85 tests/h max.; 60 tests/h consolidated (with typical test panel)
ISE	180 tests/h max.; 60-100 tests/h consolidated (photometric and ISE mixed)

Samples

Sample handling	Manually by operator
Time to first result	5-10 min (photometric measurements)
	2 min (ISE measurements)

Water purity

Minimum requirements	Electrical resistivity [MΩ*cm @ 25°C]	> 1
	Electrical conductivity [µS/cm @ 25°C]	< 1
	Silicate (SiO_2) [mg/L]	< 0.1
	Particulate matter size [µm]	n/a
	Bacteria [CFU/mL]	< 1000

Whenever the term "purified water" is used in this document, water of at least the quality specified above must be used.

Roche recommends using Reagent Grade water.

Calibrators

Roche calibrators	See the package inserts of the reagents.

Reagent bottles

Reagent bottles	20 mL maximum
Identification	Barcode
Barcode	2-D, format PDF417
Number of tests	50-200 tests, depending on the test

Cuvettes

Segments of 10 cuvettes	Manual insertion and removal of segments
Single use	Cuvettes are for single use only
Static incubation temperature in cuvette	37°C ±0.5°C

Photometer

Absorbance photometer	20 W halogen lamp
12 wavelengths	340-659 nm
Sensor	Photosensitive diode array

ISE unit

Ion-selective electrode	Indirect measurement
Sample volume	15 µL; Dilution 1:6 (1 part sample, 5 parts water)
3 Electrodes	Na, K, Cl
1 ISE Reference Electrode	

Software data handling

Operating system	• LINUX • VX Works
CPUs	Intel XScale
Memory system	• Flash ROM • DRAM • SRAM

Mass storage

External	USB memory stick
Internal	Flash ROM

Interfaces

USB1.1/2.0	For backing up data or loading data on the system (memory stick)
USB1.1/2.0	Modem
2 x RS232	Host, barcode scanner

Display

Color touchscreen	5.7 inch active matrix ($^1/_4$ VGA, 320 x 240 pixels)

Printer

Internal thermal printer	Paper width 112 mm

Software

Getting the most out of the instrument

In this chapter, you will find information on how to operate the instrument by using the touchscreen. You will find out about the concept of wizards and you are introduced to the key screens.

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Introduction

To operate the **cobas c**111 instrument, you use its touchscreen. The design and functional concept of the touchscreen support you in the way you work.

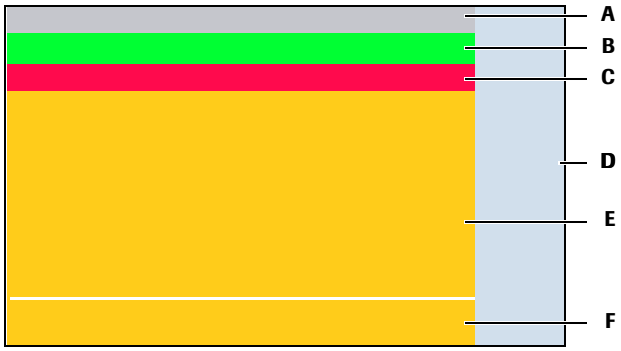
The following table lists the major items and characteristics of a **cobas c**111 screen and describes their impact on the operation of the instrument.

Screen item	Impact on operation
Screen types	Distinct screen types make it easy for you to find your way around the user interface. For example, you immediately know whether you are on a main screen or whether you are reading a message.
Screen layout	The consistent layout allows you to quickly find the required information and to locate the various display items.
Buttons	Press a button to open and close a screen or to start a function.
Colors	The color of an item on the screen points to its own status or that of the item it represents. The "traffic light" color scheme is used: • Green: Everything is OK. • Yellow: The system is working, but you need to intervene for it to continue to do so. • Red: This item does not work, you need to intervene.
Wizards	A wizard denotes a predefined sequence of screens (steps) that represent a certain task, for example defining an order. By following the suggested sequence of steps you ensure the proper execution of the tasks and functions. With some critical tasks, you need to follow the wizard exactly, right through to the end. In other cases, you may skip a step and perform it later.

Table A-8 The major items and characteristics of the touchscreen

Screen layout

All screens are based on the following layout:



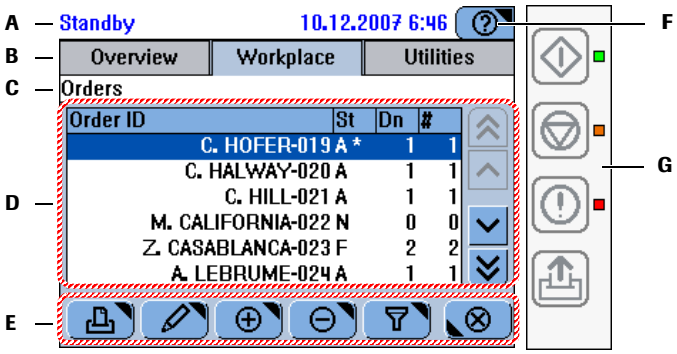
A Status area
B Tabs
C Headline
D Global action area
E Working area
F Buttons area

Figure A-34 Basic screen layout

The screen representations shown in this chapter and throughout this manual are for illustrative purposes only. The screens do not necessarily show valid data.

Depending on the function of a screen, some layout items may not be displayed.

The following is an example of a screen with the full range of display items.



A The *status line* displays the system status.
B *Tabs* represent the major work areas. You can switch to any of them any time.
C The *headline* characterizes the content or function of the screen. If the screen is part of a sequence of screens (wizard), the headline tells you where you are within this sequence.
D The *working area* displays the main content of the screen.
E The *buttons* vary depending on the content of the working area and the screen position within a series of steps (wizard).
F The *Help button* leads to concise information that is relevant to the current screen and situation.
G The *global action buttons* represent the functions that are permanently available: Start, Stop, Alarm, Line Feed. The LEDs next to them point to their status.

Figure A-35 Example of a screen

Display items

The **cobas c** 111 screens are made up of text areas and various kinds of display items such as tabs and buttons.

The following table lists the major display items and describes their use.

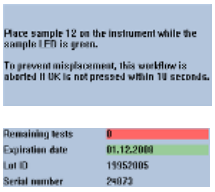
Display item		Use
	Button	Press a button to start a function. In addition, many buttons also either open a new screen or close the current screen. A triangle in the top right corner of a button tells you that a new screen will be displayed when you press the button; a triangle in the bottom left corner that the current screen will be closed.
	Global action button	The global action buttons are positioned on the right side next to the screen. The LED next to each of the buttons indicates whether the button is active or not.
	List	Press a list item to select it. (Its color turns blue.) Use the scroll buttons to display the items that are not visible.
	Text	Text usually provides information or instructions. It can be color coded to indicate its importance level.
	Tab	Tabs are used to group information into units that can be displayed on one screen.

Table A-9 Major display items

Color concept

The color of buttons and other display items tells you about the status of the display item or the item it represents.

The **cobas c** 111 instrument uses the familiar "traffic light" color scheme.

Color	Meaning for buttons
Green	The element is OK.
Yellow	Your intervention is required to ensure continuous operation.
Red	Your immediate intervention is required. Operation has stopped.
Blue	The item is selected.

Table A-10 Color concept

For details on the meaning of LED colors, see *Color interpretation for LEDs* on page A-122.

For details on the meaning of button colors, see the explanations in the relevant operation instructions.

Workflows and wizards

Screens and sequences of screens help you perform your tasks. If not all steps of a task can be performed from one screen, the workflow is realized as a sequence of screens, a so-called *wizard*. **cobas c** 111 wizards do not usually *force* you to perform a task at a certain stage, they just make your work easier.

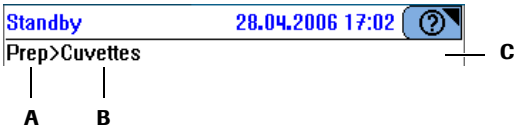
Navigation

Moving from screen to screen

You move from screen to screen with the help of buttons.

Knowing where you are

Screens on which you perform tasks provide a headline that displays the navigation path of the current screen.



A Button where you started
B Current position in the workflow
C Headline

Figure A-36 Headline with navigation path

For an overview of the navigation buttons, see *Navigation functions* on page A-126.

Working with the user interface

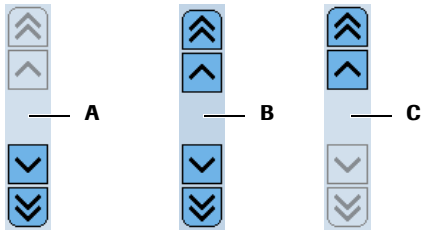
Adjusting the touchscreen

With a touchscreen, it is important that the point where you press the screen corresponds exactly with its hardware equivalent. If this were not the case, pressing a screen item such as a button might not lead to the expected result.

See *Adjusting the touchscreen* on page B-130.

Scrolling

If not all text or all list elements fit on one screen or display area, use the scrolling function to display the hidden content.



A You are on the first page. You can scroll down.

B There is text both before and after the currently displayed text. You can scroll up and down.

C You are on the last page. You can scroll up.

Figure A-37 Scroll bars

Scroll to the previous page.

Select the previous line and scroll if necessary.

Select the next line and scroll if necessary.

Scroll to the next page.

Expanding and collapsing lists

In hierarchically structured lists, you initially see only the top level entries. List items that contain (but hide) lower levels of entries are marked with ⊞. List items that display lower levels of entries are marked with ⊟.

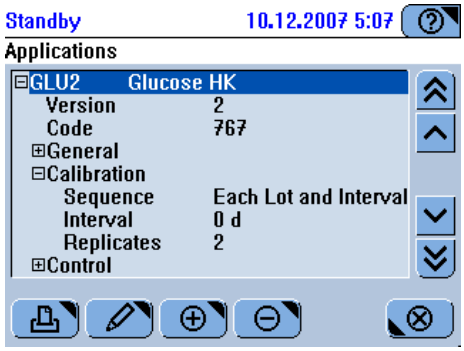


Figure A-38 Hierarchically structured list

► To expand a list

1 Select a list item marked with ⊞.

2 Press ⊞ again or press [ ].

3 Use the scrollbar, if required, to display the items you are interested in.

■

► To collapse a list

1 Select a list item marked with ⊟.

2 Press ⊟ again or press [ ].

■

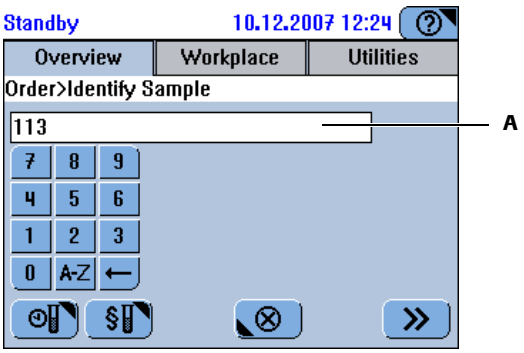
Typing text

There are dedicated screens for typing alphanumeric and numeric characters.

You can choose from the following screens:

- Alphanumeric upper case
- Alphanumeric lower case
- Special characters
- Numeric characters

Numeric keyboard



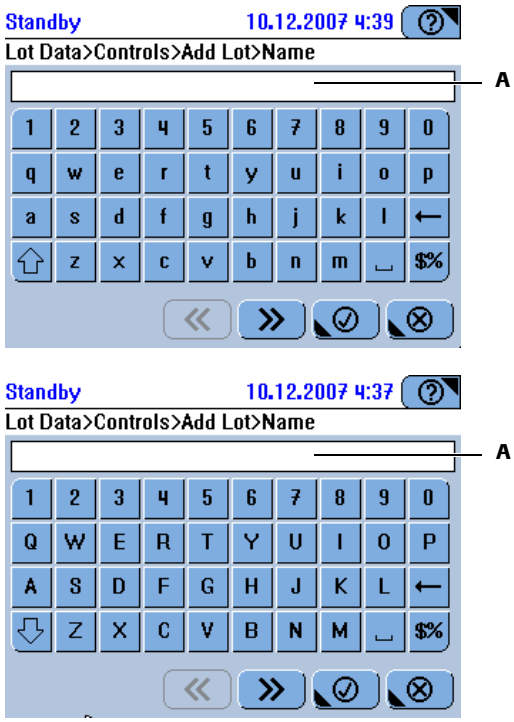
A Typed text

Figure A-39 Numeric keyboard screen

← Delete the last character displayed in the text line.

A-Z Switch to the uppercase alphanumeric keyboard.

Alphanumeric keyboards



A Typed text

Figure A-40 Upper and lowercase alphanumeric keyboard screens

⇩ Switch to the lowercase keyboard.

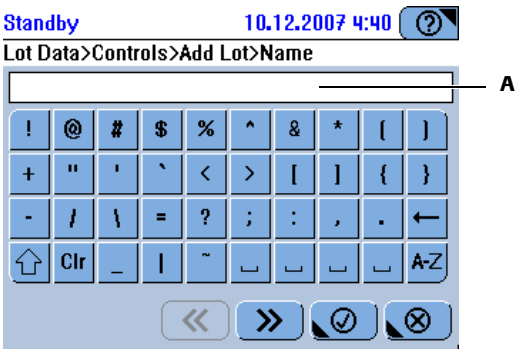
⇧ Switch to the uppercase keyboard.

← Delete the last character displayed in the text line.

$% Switch to the special characters keyboard.

␣ Press to insert a space.

Special characters keyboard



A Typed text

Figure A-41 Special characters keyboard screen

Switch to the lowercase alphanumeric keyboard.

A-Z Switch to the uppercase alphanumeric keyboard.

← Delete the last character displayed in the text line.

␣ Press to insert a space.

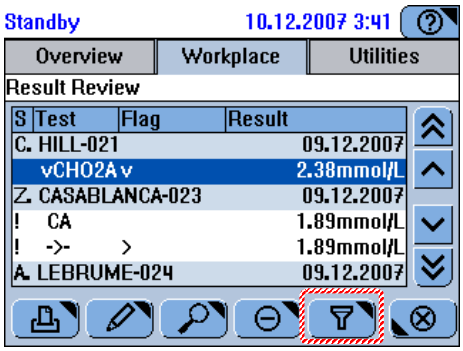
Using the filter function

In many lists you can apply a filter, that is, you can select predefined criteria for generating a selection of entries.

The way to apply a filter is the same in all screens where a filter is available. Here is an example:

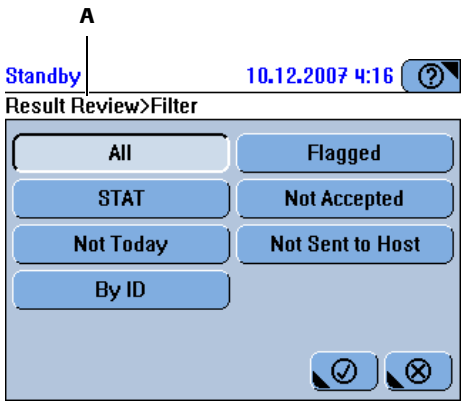
► To apply a filter to a list

1 Display the list.



2 Press .

A screen is displayed for selecting the filter criterion.



A In the status line, the screen is indicated where you pressed .

3 Choose one of the filter options.

4 Press .

The list is displayed again. It now contains only the entries that comply with the criterion you just applied by pressing its button.

■

After you have applied a filter, the criterion name will appear as part of the **List** button, for example on screens for deleting data. If you used the **Not Accepted** filter criterion, the **List** button would be called **List [Not Accepted]**.

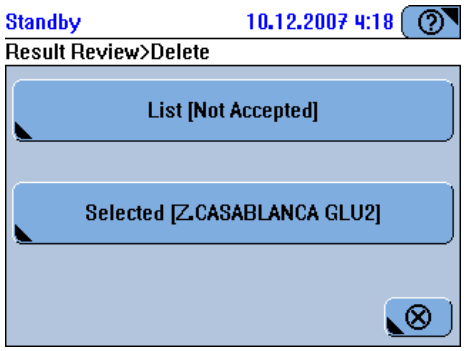


Figure A-42 List button names

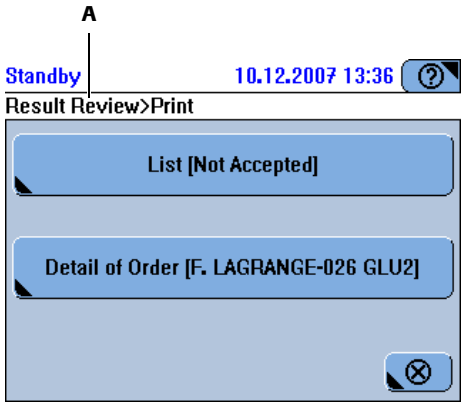
Printing information

On many screens, you can print the contents of the working area on the built-in printer. In many cases, a screen is first displayed for selecting the kind of data you want to print. In these cases, the print button is marked with a triangle in the top right corner .

► To print information

1 Press .

If filter criteria are available, a screen is displayed for selecting what data you want to print. For example:



A In the status line, the screen is indicated where you pressed .

2 Choose one of the print options.

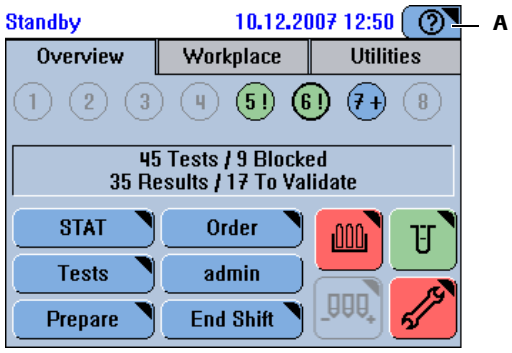
The appropriate data is automatically selected and printed.

Choose > to terminate the printing task, if required.

■

Using online Help

The Help button is a permanent feature of all screens.

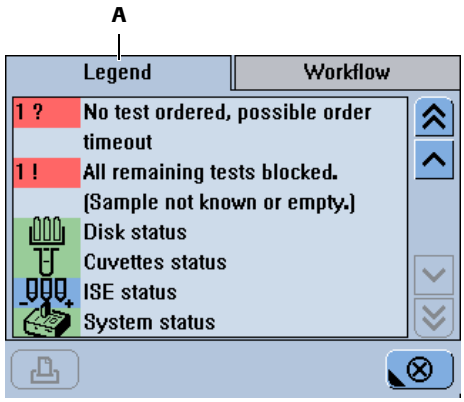


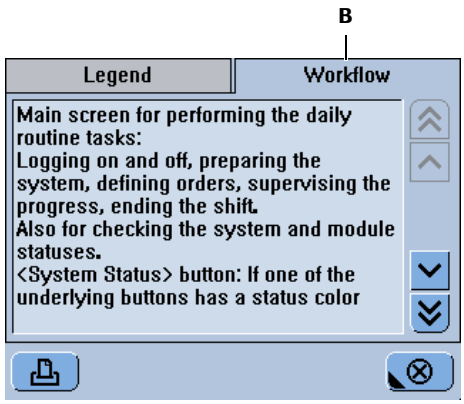
A The Help button is always in the top right corner of the screen.

Figure A-43 Permanent Help button

► To display the Online Help

1 Press .





A The **Legend** tab describes the buttons and their colors.

B The **Workflow** tab provides additional information on items on the screen or on actions you can perform.

Figure A-44

2 Use the scroll bar to display the hidden information.

For details on scrolling, see *Scrolling* on page A-75.

■

Messages

Messages are displayed in two ways:

- Immediate feedback on user actions is displayed in a pop-up *message screen*.
- Information concerning a problem that occurred during operation is reported in the *alarm monitor*.

Message screen

Message screens are displayed automatically as soon as the message is generated.

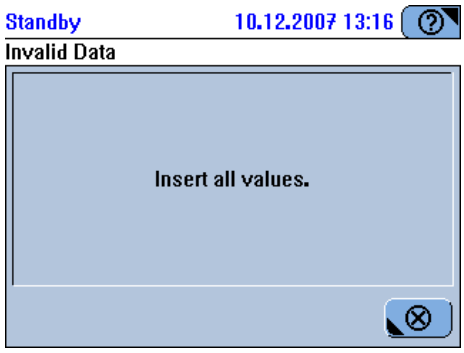


Figure A-45 Message screen

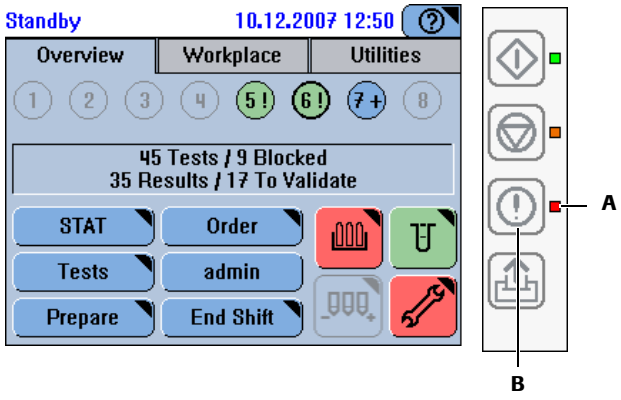
Read the message and press ⊗ to close the screen.

Alarm monitor

Messages concerning an irregularity that occurred during operation can be viewed in the alarm monitor. The alarm LED alerts you when such messages are generated. It is turned off when all alarm messages are confirmed.

The Alarm button ⓘ is always active, even if nobody is logged on the system.

Alarm button and LED



A Alarm LED **B** Alarm button

Figure A-46 Alarm LED

Interpreting the alarm LED

No color, off There are no unconfirmed alarm messages.

Yellow There is at least one unconfirmed alarm message. You need to deal with it as soon as possible.

Red There is at least one unconfirmed alarm message. You need to deal with it immediately, processing may not be able to continue unless you do so.

Acoustic signal An acoustic signal is sounded when an alarm is generated. You can adjust the volume (**Utilities** > **Configuration** > **System** > **Volume**).

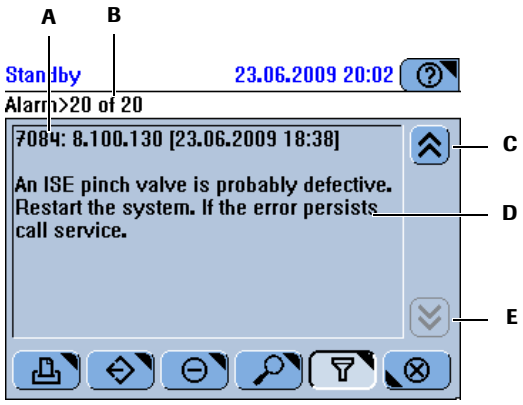
► To display alarm messages

1 Press .

2 Use to limit the number of messages that are contained in the list.

3 Select the message you are interested in.

Alarm message

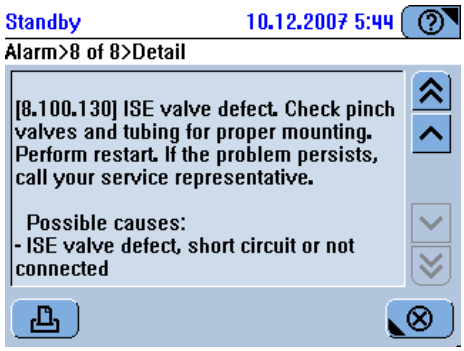


A Alarm ID
B Total number of messages in the list.
C Display the previous alarm message.
D Problem description and short remedy suggestion
E Display the next alarm message.

Figure A-47

4 Press to display the detailed message.

Detailed alarm message



For details on handling alarm messages, see *Reacting to alarm messages* on page D-7.

■

Key screens

The screen representations shown in this chapter and throughout this manual are for illustrative purposes only. The screens do not necessarily show valid data.

The main screen is divided into tabs. These tabs represent distinct work areas.

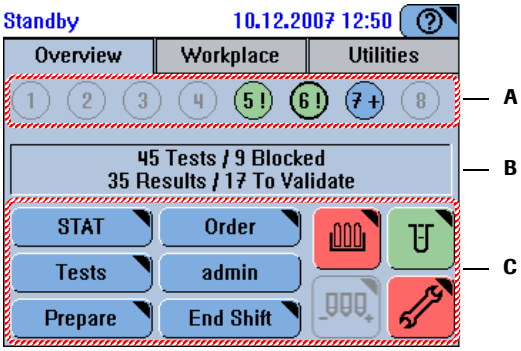
➔ The **Overview** tab is your main work area when performing the daily routine tasks.

- Use the **Workplace** to gain information on orders and the corresponding results. You can also start the lot handling functions from this tab.
- Use the **Utilities** tab to perform tasks that are not normally part of the routine analysis workflow. Typically, these would be administration and maintenance tasks.

The following sections describe the key screens of these tabs and point out the main tasks you can perform on them.

Overview tab

The **Overview** tab is your main work area when performing the daily routine tasks.



A Tube icons
B Status of current order processing
C Buttons

Figure A-48 **Overview** tab

Show details about the order for this sample.

STAT Define STAT orders.

Order Define routine orders.

Tests Check the status of the currently installed tests.

Log off, (Log on) Log off or on the system.

If somebody is logged on, your user name is displayed, for example **admin**; if nobody is logged on, **Log on**.

Prepare Perform the preliminary tasks at the beginning of a shift.

End Shift Perform the necessary tasks when ending the shift.

Check the status of the reagent disk.

The reagents are OK.

Fewer than 10% of tests are left for a reagent set, or its expiration date has passed.

No or unidentified disk on board.

A reagent set is not complete or a reagent is empty.

Check the status of the cuvette segments currently loaded on the rotor.

More than one segment is available.

The last available cuvette segment is in use.

No cuvettes are available.

System Status

The **System Status** button displays both the icon and the color of one of the buttons of the underlying system status screen (see *System status* on page A-95).

The icons are first prioritized by color, first priority being red, followed by yellow and green, and then according to the sequence in which they are listed below.

This button can show either of the following icons.

Analyzer (main cover)

Reagent cooler and cuvette ring temperature

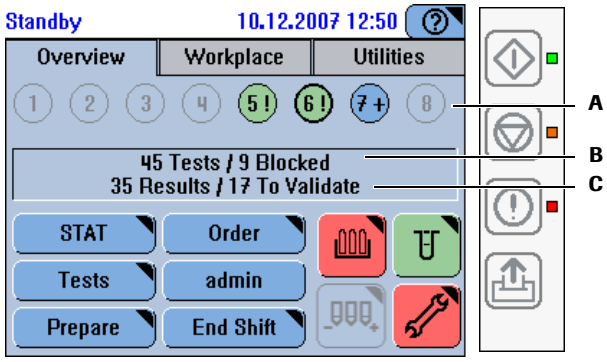
Sample area ventilation

External fluid containers

Maintenance

Printer

Sample overview



A Sample tube buttons
B Open orders
C Results

Figure A-49 Sample tube status on the **Overview** tab

1 The number in the button indicates the position on the sample area.

A sample tube button with a wide edge symbolizes a STAT order.

All tests are completed and their results are accepted.

All tests are pipetted.

All tests are completed but not yet accepted.

All remaining tests are blocked for one of the following reasons:

- There is not enough sample fluid.
- The sample is not identified.

There is no sample on this position.

Tests are ordered. Processing has not yet started.

Tests are ordered, processing has started.

The sample is identified, but no tests were ordered yet.

If working in **Order Query Mode**: The order could not be obtained from the host.

Orders

➔ Overview > Order

Press **Order** to define routine orders.

The process of defining an order, and consequently which screens are displayed, depends on how your **cobas c** 111 instrument is integrated in your laboratory infrastructure (barcodes, host connection).

Identifying samples

➔ Overview > Order

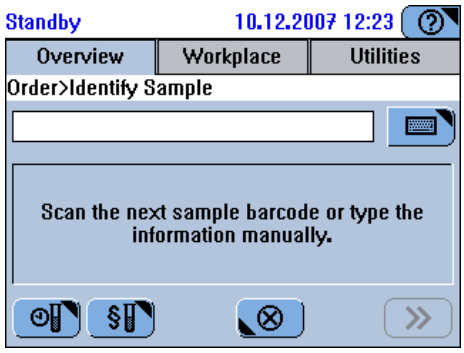


Figure A-50

Order Interval QC.

Order Default QC.

Typing the sample ID

➔ Overview > Order

(If you work with barcodes, additionally press .)

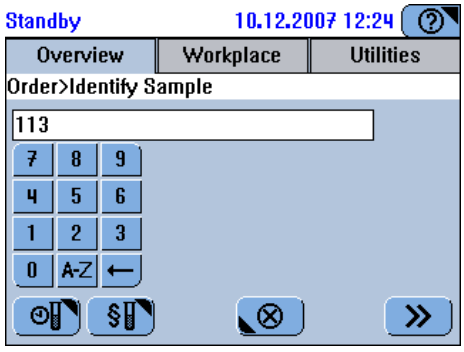


Figure A-51

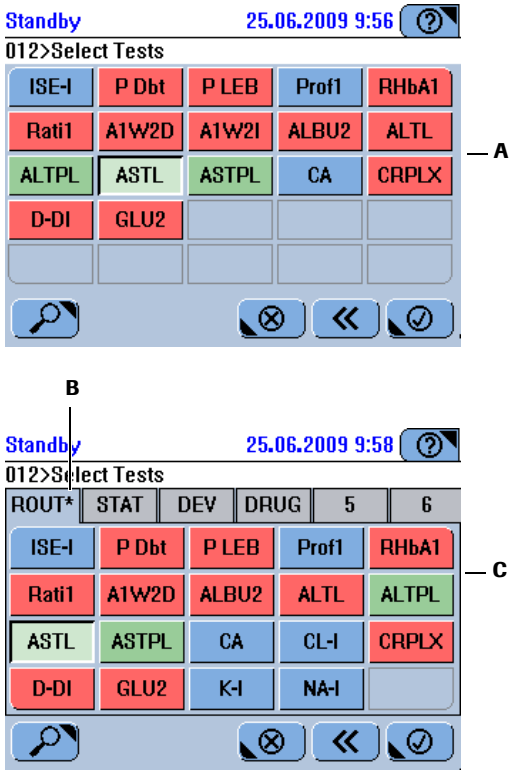
For information on how to use the keyboard screens, see *Typing text* on page A-76.

Order Interval QC.

Order Default QC.

Selecting tests, profiles, and ratios,

➔ **Overview** > **Order** > identify sample



A **Easy** mode test-board, all tests fit on one screen.

B Tabs marked with an asterisk contain selected tests.

C **Full** mode test-board. The tests are grouped in tabs.

Figure A-52 Test selection screens

Tabs are used to group information into units that can be displayed on one screen. The system administrator can define up to six test tabs, name them and assign tests, profiles, and ratios to them.

The tests, profiles, and ratios are sorted alphabetically. Profiles and ratios precede the tests, and they adopt the color of their tests.

The test is on board and ready for use.

CA The test has already been pipetted.

The test is blocked.

The expiration date of the test has passed.

There are only few tests left.

A QC is due or its result has not been accepted.

A more recent version of the application has been imported.

For a development channel: An extra wash cycle is missing.

The test is defined but not on board.

A required diluent or cleaner is not on board.

Display a screen that contains information on the status of each test.

STAT

➔ **Overview** > **STAT**

Press **STAT** to define urgent (short turn-around time) orders.

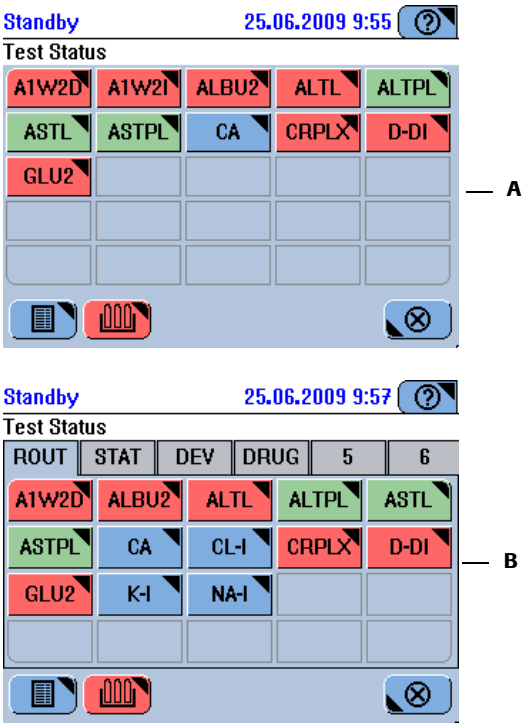
The process of defining a STAT (short turn around time) order is identical to that of defining a routine order. The difference lies in the scheduling of the tasks. When a STAT order is defined, it will be the next order to be processed, irrespective of what routine orders already exist. Existing STAT orders are finished first.

Tests

Displaying the test overview

➔ Overview > Tests

Tabs The tabs are displayed if you work with the order mode **Full**. They represent user-defined test panels. If you work with the order mode **Easy**, all tests are on one panel and there are no tabs.



A Test selection screen in order mode **Easy**. **B** Test selection screen in order mode **Full**.

Figure A-53 Test selection screen

The color of a test button represents its status:

The test is on board and ready for use.

The test is blocked for one of the following reasons:

- The calibration is due or failed.
- For the reagent set, the number of available tests is 0, or a reagent bottle is missing (incomplete reagent set).
- Initial calibration is required.

The expiration date of the test has passed.

There are only few tests left.

A QC is due or its result has not been accepted.

A more recent version of the application has been imported.

For a development channel: An extra wash cycle is missing.

The test is not on board.

A required diluent or cleaner is not on board.

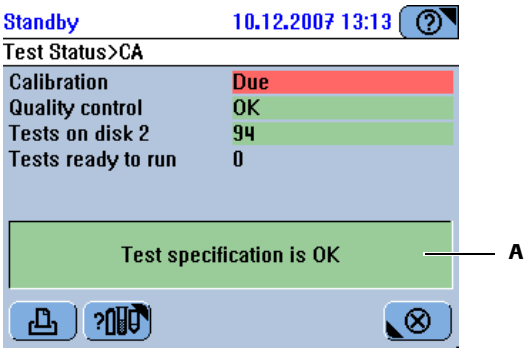
<xyz> Display detailed information on the status of this test.

Display a list of all defined tests, together with information on their status.

Handle the reagent disk that is currently on board.

Displaying test details

➔ **Overview** > **Tests** > test button



A Status description of the test

Figure A-54 Details on a test

The color of the text indicates whether you need to react to the information, and if so, with which urgency you need to deal with the issue.

Calibration Information on the calibration status.

Quality control Information on the QC status.

Tests on disk Total number of tests that are currently available. (There might be more than one reagent set for this test on board.)

Tests ready to run Number of tests that could be performed, taking into account all disks known to the system. (The reagent sets have been calibrated and are ready for use.)

Print the test status information.

Show the fluids that were used for generating this result, together with their lot information.

Profiles are user defined sets of tests. They are represented like any other test.

Log off

➔ **Overview** > button with your user name

Log off the system.

You can log off any time, even while the system is processing orders.

Prepare

➔ **Overview** > **Prepare**

Start the **Prepare** wizard to perform the preliminary tasks at the beginning of a shift.

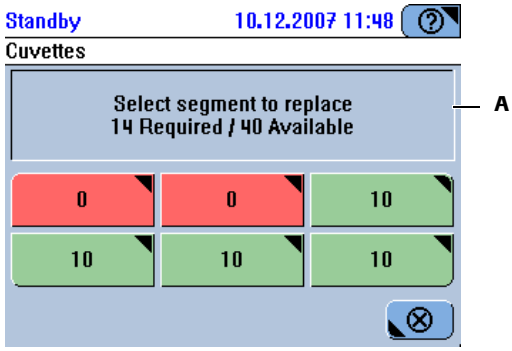
End shift

➔ **Overview** > **End Shift**

Start the **End Shift** wizard to perform the tasks necessary for ending the shift.

Cuvette status

➔ **Overview** > .



A Overview of required and available cuvettes

Figure A-55 Cuvette status

The six cuvette segments are represented by buttons. The number in the button indicates how many cuvettes are free to be used.

Press a segment button to exchange the corresponding segment.

The segment buttons are color coded:

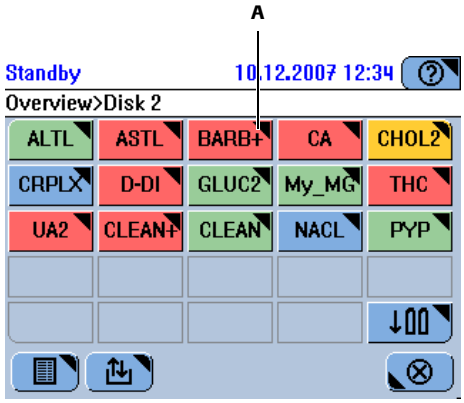
All cuvettes are used.

Up to two cuvettes are free to be used.

More than two cuvettes are free to be used.

Disk and reagent status

➔ Overview >



A A plus (+) indicates that there is already an active identical reagent set on board. (This icon is displayed as soon as the first bottle of the set is loaded.)

Figure A-56 Reagent sets loaded on the reagent disk

The color of a reagent set button represents the status of the set:

The reagent set is on board, but it is blocked for one of the following reasons:

- The number of available tests is 0.
- The set is incomplete.
- The test needs calibrating.
- There is no application that uses this reagent set.

There are fewer than 10% of tests are left for this set.

The expiration date has passed.

The reagent set is on board and ready for use.

Display detailed information on the status of this test.

Load a reagent set.

Display a list with all tests on board, together with information on their status.

On the list, the following abbreviations are used to indicate the status of the reagent set:

- C: Calibration missing
- E: Empty
- I: Incomplete
- N: Not used
- L: Low
- X: Expired

Handle the reagent disk.

ISE status

This button is only active if your instrument is equipped with an ISE unit.

➔ Overview > .

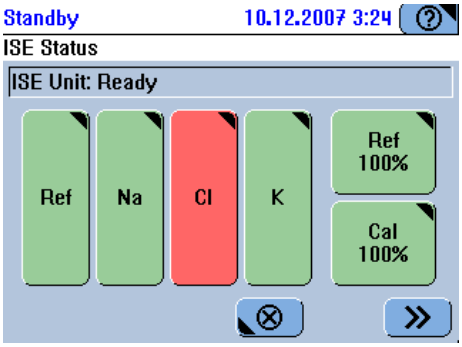


Figure A-57 ISE status

Na, K, Cl, Ref Display detailed information on the status of the electrode.

The expiration date of an electrode has passed.

The electrode is ready for use.

Calibration required. (Does not apply to the reference electrode.)

After installing a new electrode, the Electrode Service maintenance action is due.

Cal, Ref Display detailed information on the status of the ISE fluid bottle.

No fluid registered by a sensor. (Operation has stopped.)

Calibration required.

The fluid level in the bottle is low. (Operation will proceed until one of the sensors detects that there is no fluid.)

There is sufficient fluid.

Display the placement list for actions that are due, for example calibration or electrode service.

System status

➔ Overview > , or , or , or , or , or

The system status button on the **Overview** tab displays both the color and the icon of one of buttons of the system status screen. (The icons are first prioritized by color, first priority being red, followed by yellow and green, and then according to the sequence in which they appear on the screen.)

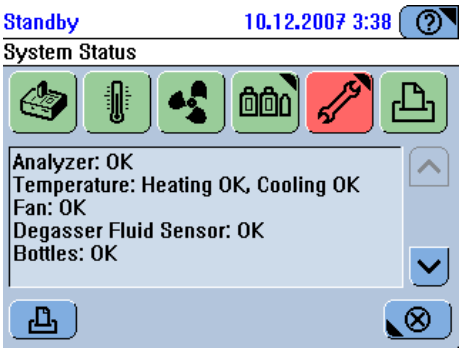


Figure A-58 System status

Check the texts for the status of hardware items and on IDs of installed software.

Status of the instrument.

The main cover is open.

A development channel application is run without using extra wash cycles.

- Roche strongly recommends to always use extra wash cycles with development channel applications, and also to always load extra cleaner when tests with extra wash cycles are used.
- Roche Diagnostics Ltd. assumes only limited liability when using the **cobas c** 111 instrument in conjunction with the **cobas c** 111 Development Channel Programming Software. For detailed information on this matter refer to the latest version of the Development Channel Registration Form **cobas c** 111 and the **cobas c** 111 Development Channel Operator's Manual.

Temperature status for reagent cooler and cuvette ring.

The temperature is outside the acceptable range.

Status of the sample area fan.

The fan is not running.

Display information on the fill status of each of the external bottles.

The color of the underlying buttons is displayed.

See *Checking the external bottles* on page A-96.

Display the maintenance actions list.

The color of the most urgent maintenance action is displayed.

See *Maintenance* on page A-110.

Status of the printer paper.

The printer is out of paper.

Checking the external bottles

➔ Overview > > .

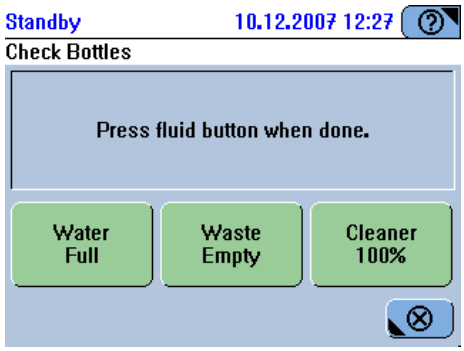


Figure A-59 Status of external containers

Water button Press to confirm that you have refilled the external water container.

The water container was last filled up less than one day ago.

The water container was last filled up more than one day ago. (The system does not monitor the filling level. It is up to the operator to fill up the water container regularly.)

A fluid sensor detected that there is no water in the instrument tubing. No new tests can be processed, started tests may have to be restarted after refill.

Waste button Press to confirm that you have emptied the external waste container.

The waste container was last emptied less than one day ago.

The waste container was last emptied more than one day ago. (The system does not monitor the filling level. It is up to the operator to empty the waste container regularly.)

Cleaner button Press to confirm that you have exchanged the external cleaner bottle.

The cleaner is OK.

The cleaner level is down to 10% or lower. See the % indication.

A fluid sensor detected that there is no cleaner in the instrument tubing. No new tests can be processed, started tests may have to be restarted after replacing the bottle.

Workplace tab

The **Workplace** tab leads to information on orders and the corresponding results.

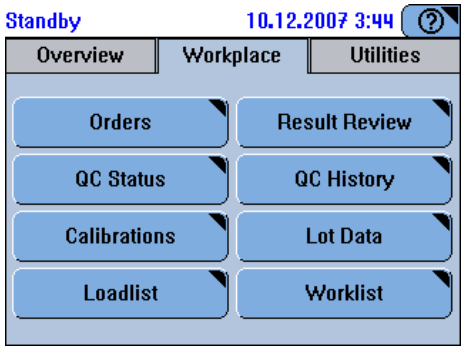


Figure A-60 **Workplace** tab

Orders View and handle orders.

Result Review View and validate sample results.

QC Status View and validate active QC results.

QC History View QC results—on individual screens—of the current or the previous calendar month, or those generated before the previous month.

Calibrations View, validate and delete calibration results.

Lot Data Define and change calibration and QC lot data by reading barcodes or typing the values.

Loadlist List of tests that are ready to be performed.

Worklist Information on tubes currently placed on the sample area.

Orders

➔ Workplace > Orders

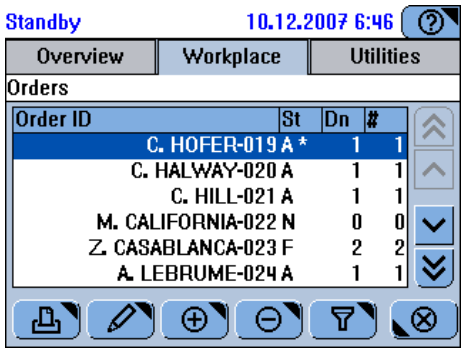


Figure A-61 Orders list

St column Status

A	Accepted	B	All blocked
C	Created	D	Deleted
F	All calculated	N	No test order
O	+Order time-out	P	All pipetted
R	Ready	S	Some blocked
T	Rerun time-out	U	Unknown

blank: Done (all tests measured and results accepted)

STAT orders are marked with an asterisk (*).

Dn column Number of tests done for this order.

 # column Total number of tests required for this order.

Print the content of the orders list.

You can choose one of the following options:

- **List** (All orders in the list with their results. If a filter was applied, the list would contain only the results that fulfill the filter criterion, and the filter criterion would be part of the button name.)
- **Detail of Order** (The currently selected order with its results.)

Change the selected order.

Define a new order.

Delete orders.

You can choose what kind of orders should be deleted:

- **List** (All orders in the list. If a filter was applied, the list would contain only the orders that fulfill the filter criterion, and the filter criterion would be part of the button name.)
- **Selected** (Delete the selected order with its results.)

Apply filter criteria to the orders list.

You can choose one of the following criteria:

- All
- Incomplete
- STAT
- Not Finished
- Not Today
- By ID

Result list

➔ Workplace > Result Review

Reviewing sample results

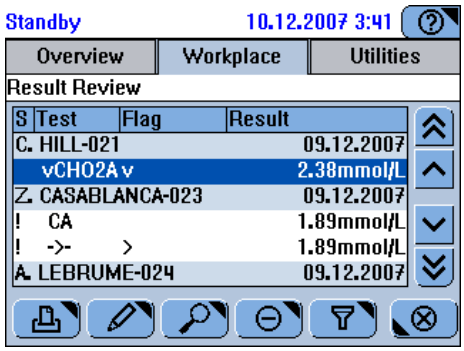


Figure A-62 Result list

This line contains result information.

This line contains sample information.

This line is selected.

S column Status

!: This result has not yet been accepted.

- STAT orders are marked with an asterisk (*).
- The time indication represents the time when the order was defined.

Print results. You can choose one of the following options:

- **List** (All results in the list. If a filter was applied, the list would contain only the results that fulfill the filter criterion, and the filter criterion would be part of the button name.)
- **Detail of Order** (All results of the associated order)

Validate the results.

You can choose one of the following options:

- **Repeat** (Perform the same test with identical dilution.)
- **Rerun** (Perform the same test with different dilution.)
- **Accept**
- **Retransmit**

Display details of the selected result.

Delete results.

You can choose what kind of result should be deleted:

- **List** (All results in the list. If a filter was applied, the list would contain only the results that fulfill the filter criterion, and the filter criterion would be part of the button name.)
- **Selected**

Apply filter criteria to the results list.

You can choose one of the following criteria:

- **All**
- **Flagged**
- **STAT**
- **Not Accepted**
- **Not Today**
- **Not Sent to Host**
- **By ID**

QC status list

➔ Workplace > QC Status

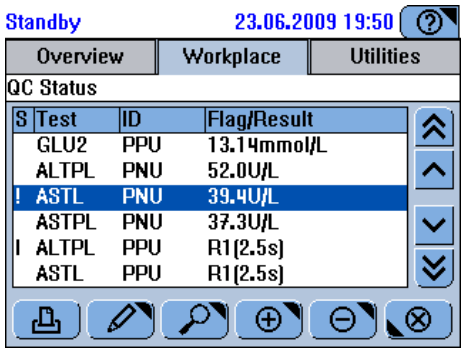


Figure A-63 QC status list

The entries are grouped first by test name, then by control.

S column Status

!: The result has not been accepted yet.

I: The result was ignored.

@: The result has not been transmitted yet.

***Flag/Result* column** Result if no flag was generated.

Flag with highest priority, if flags were generated.

Order status if the control measurement has not been performed yet.

Previous Lot indicates that controls of more than one lot were used.

Print QC results.

Validate the QC results.

You can choose one of the following options:

- **Accept**
- **Ignore**
- **Retransmit**

Display details of the selected QC result.

Define a new QC order.

Delete QC results.

You can choose what kind of result should be deleted:

- **All**
- **All Accepted**
- **Selected**

QC history

The QC history provides—on individual screens—information on the QC results of the current and the previous calendar month as well as on results generated before the previous month.

A graphic representation of the results provides a convenient way for comparing results over a period of time.

➔ **Workplace** > **QC History**

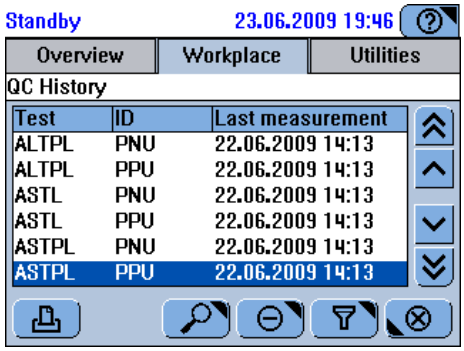


Figure A-64 QC history

The list contains, for each test and control, the latest QC result. The entries are grouped first by test name, then by control.

Last Measurement column Date and time of the most recent result.

Previous Lot indicates that control was performed after a QC lot change.

Print QC results.

Display a graphic representation of the QC results.

Delete QC results.

You can choose what kind of result should be deleted:

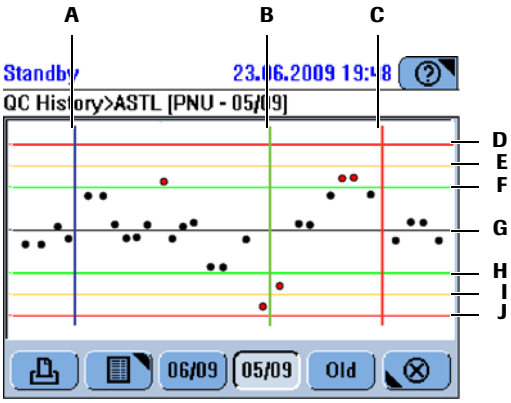
- **List** (All results in the list. If a filter was applied, the list would contain only the results that fulfill the filter criterion, and the filter criterion would be part of the button name.)
- **Older than Previous Month**
- **Selected**

Apply filter criteria to the QC results list.

You can choose one of the following criteria:

- **All**
- **Current Lot**
- **Previous Lot**

➔ Workplace > QC History > 🔍



A	Calibrator lot change	**F**	+2s
B	Reagent set change	**G**	Mean value
C	QC target value change	**H**	-2s
D	+3s	**I**	-2.5s
E	+2.5s	**J**	-3s

Figure A-65 QC history graphic

Print the graphic.

Display the results in a table.

The results are sorted chronologically, relevant events (QC lot change, reagent set change, QC target value change) precede the results.

Month button Display the results of the month indicated on the button.

Old Display the results generated before the beginning of the previous month.

Calibrations list

➔ Workplace > Calibrations

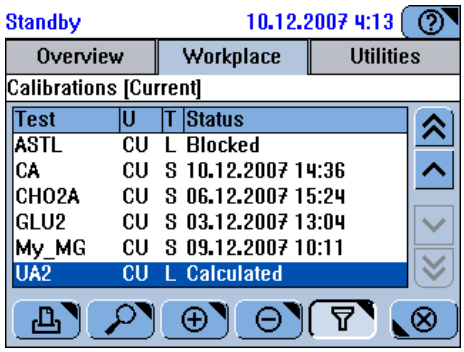


Figure A-66 Calibrations list

U column Use of calibration

CU: Current calibration

SB: Standby calibration

OB: Obsolete calibration

T column Calibration type

L: Lot calibration

S: Set calibration

***Status** column* The date indicates when the results were accepted. If flags were generated for the result, the flag with the highest priority is displayed. In all other cases, the order status is displayed.

Print calibration results.

You can choose one of the following options:

- **List** (If a filter was applied, the list would contain only the results that fulfill the filter criterion, and the filter criterion would be part of the button name.)
- **Detail of Calibration**.

Display details of the selected calibration.

Validate the calibration.

You can choose one of the following options:

- **Accept Set**
- **Accept Lot**
- **Repeat**
- **Use Old**

  Use **Use Old** to override and reset the calibration due date and to continue using the old calibration results.

Define a new calibration order.

Delete the selected calibration result.

Apply filter criteria to the calibration results list.

You can choose one of the following criteria:

- All
- Current

Lot data

➔ **Workplace > Lot Data**

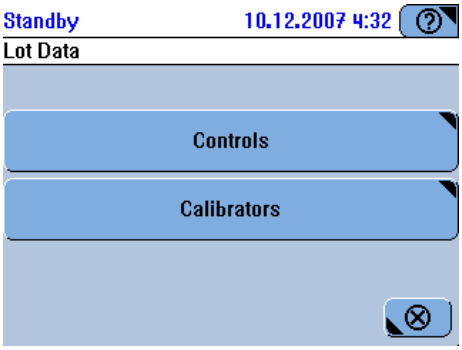


Figure A-67 Select lot type

Choose the kind of material for which you want to handle lot data.

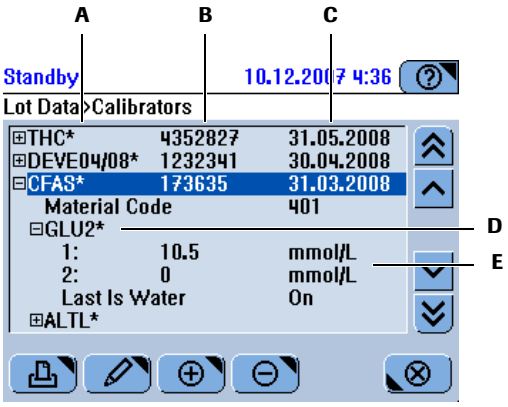
Controls Handle control lots.

Calibrators Handle calibrator lots.

Lot list

➔ **Workplace** > **Lot Data**, then choose a lot type.

The content of this list depends on the selected lot type. The following screen is an example of calibrator lot data.



A Calibrator name.
Asterisk: The lot data were changed by the operator.
Not installed: The associated application is not installed.

B Calibrator lot

C Expiration date

D Associated test

E Lot values

Figure A-68 Calibrator lot data

Print lot data.

With a calibrator selected: Expand or collapse the list.

With a test selected: Expand or collapse the list.

With a value selected: Change the value.

With a calibrator selected: Add a lot.

With a test selected: Assign a test to the lot.

With a value selected: Not active.

With a calibrator selected: Delete the lot values of the calibrator.

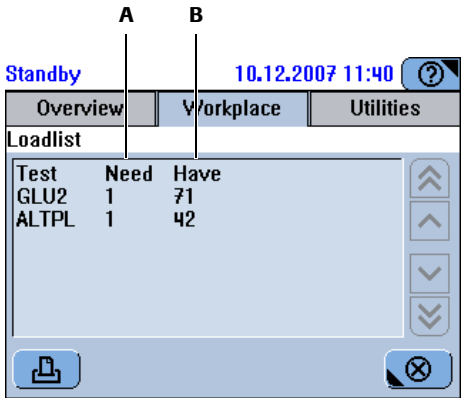
With a test selected: Delete the lot values of the test.

With a value selected: Not active.

Loadlist

List of tests that are ready to be performed.

➔ Workplace > Loadlist



A Number of due pipettings **B** Number of available pipettings

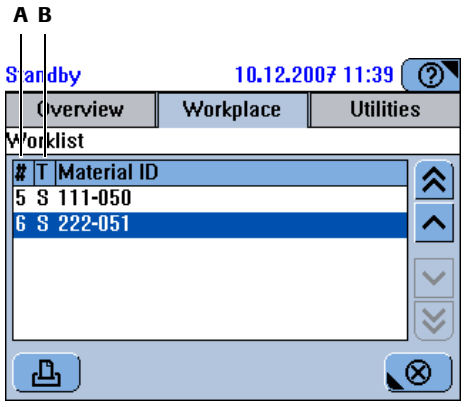
Figure A-69 Loadlist

Print the loadlist.

Worklist

The worklist shows all tubes currently placed on the sample area.

➔ Workplace > Worklist



A Position on sample area

B Fluid type:

- **A**: Activator
- **C**: Calibrator
- **D**: Diluent
- **E**: ISE Etcher
- **P**: ISE Deproteinizer
- **Q**: Control
- **S**: Sample
- **U**: Unknown

Figure A-70 Worklist

Print the worklist.

Utilities tab

Use the **Utilities** tab to perform tasks that are not normally part of the routine analysis workflow. Typically, these are administration and maintenance tasks.

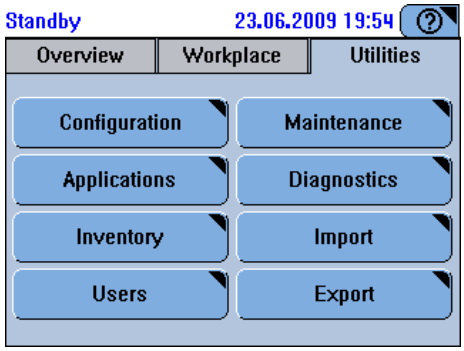


Figure A-71 **Utilities** tab

Configuration View and change configuration values.

Maintenance Select and perform maintenance actions.

Applications
- Handle applications and their definitions.
- Handle extra wash cycles
- Display, export and import the mapping table for test IDs of the **cobas c** 111 instrument and the laboratory information system.

Diagnostics Perform diagnostics actions.

Inventory Display information on bottle sets that are currently defined on any disk used on the **cobas c** 111.

Import Import application data, software updates, the complete content of a database, certificates, extra wash cycle definitions, reagent mixing rules, or a new user interface language.

Users Define users and manage their user rights.

Export Export the complete content of the database, the full results, and log files.

Configuration

➔ Utilities > Configuration

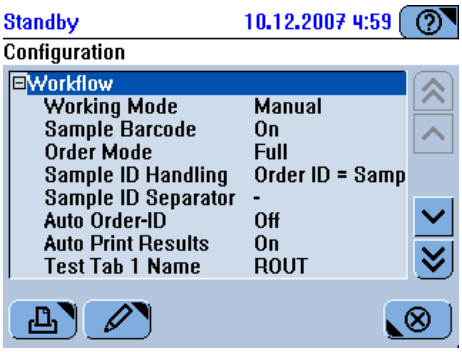


Figure A-72 Configuration table

There are list items of a lower level. Select the item marked with ⊞ and press ⊞ again to expand the list and display the items.

The list is expanded. Select the item marked with ⊟ and press ⊟ again to hide the items.

Print configuration data.

You can choose one of the following options:

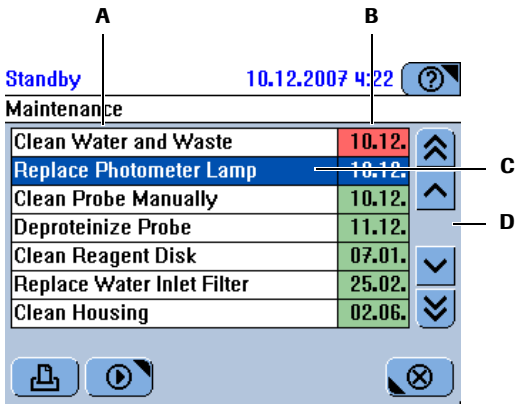
- All
- **Selected** (Print the settings of the selected configuration group.)

With an item selected: configure the selected item.

With a group title selected: expand or collapse the list.

Maintenance

➔ Utilities > Maintenance



A Maintenance action name

B Due dates, in ascending order

C This maintenance action is selected.

D Use the scroll bar to display the maintenance actions that are currently hidden.

Figure A-73 Maintenance actions list

The maintenance actions are listed according to the urgency with which they need to be performed.

No action is currently required.

This maintenance action should be performed on the next major maintenance day.

The defined maintenance interval has expired. Perform this maintenance action now.

Perform the selected maintenance action.

If you interrupt the performing of a maintenance action that was due, its status will remain due, and you need to fully re-perform the action later.

Applications related functions

➔ Utilities > Applications

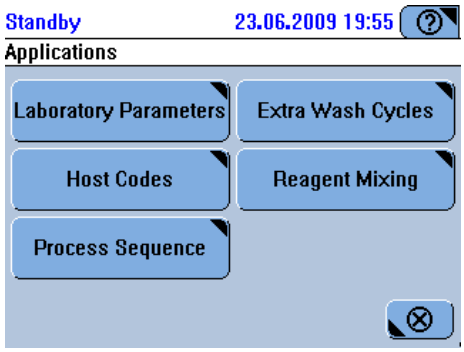


Figure A-74 Applications functions

Laboratory Parameters Handle the definitions of the installed applications and import and install new applications.

Extra Wash Cycles Handle and install extra wash cycles.

Host Codes Display, export and import the mapping table for test IDs of the **cobas c** 111 instrument and the laboratory information system.

Reagent Mixing Display, print, and delete mixing rules.

Process Sequence Prioritize individual tests.

Applications

➔ Utilities > Applications > Laboratory Parameters

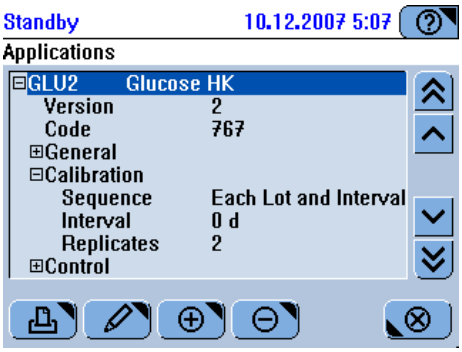


Figure A-75 Applications table

There are list items of a lower level. Select the item marked with ⊞ and press ⊞ again to expand the list and display the items.

The list is expanded. Select the item marked with ⊟ and press ⊟ again to hide the items.

Print the application list.

With an item selected that is preceded by ⊞ or ⊟: expand or collapse the list.

With any other item selected: change the selected item.

Import an application.

Define a new profile or a ratio.

Install an application

Uninstall an application.

Delete a profile or uninstalled application.

Extra wash cycles

➔ Utilities > Applications > Extra Wash Cycles

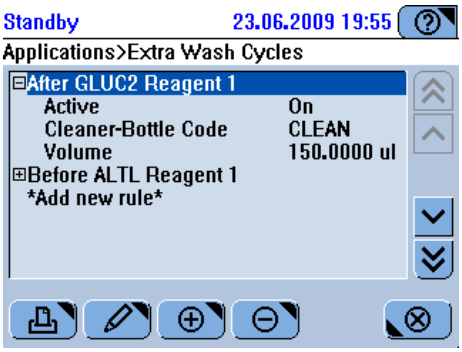


Figure A-76 Extra wash cycles table

Print the selected or all extra wash cycle definitions.

With an item selected that is preceded by ⊞ or ⊟: expand or collapse the list.

With any other item selected: change the selected item.

Import a new extra wash cycle.

Delete the selected extra wash cycle.

Host codes

➔ Utilities > Applications > Host Codes

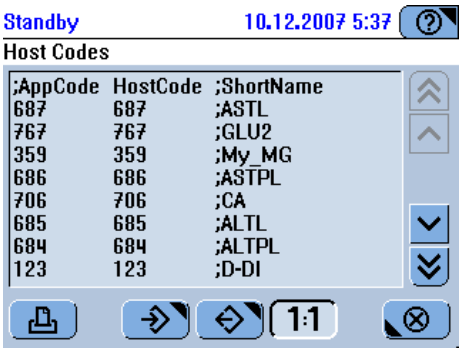


Figure A-77 Code mapping table

Print the mapping table.

Import the mapping table.

Export the mapping table as a text file.

Use the same test IDs for the **cobas c** 111 instrument and the laboratory information system.

Reagent mixing

➔ Utilities > Applications > Reagent Mixing

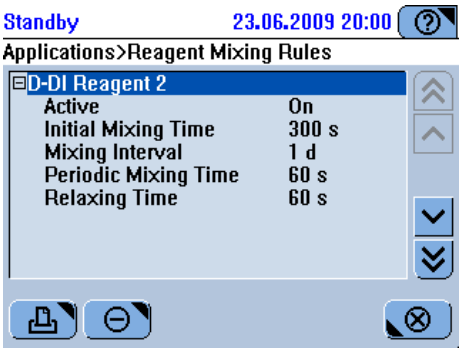


Figure A-78 Reagent mixing rules table

Print the selected or all mixing rules.

Delete the selected mixing rule.

Process sequence

➔ Utilities > Applications > Process Sequence

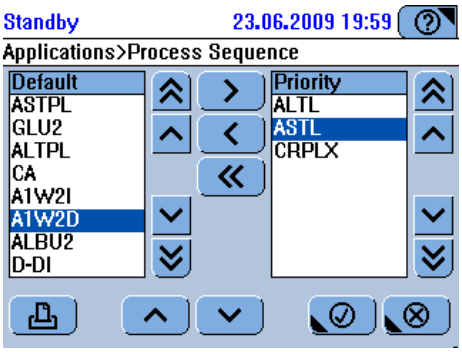


Figure A-79 Processing priority table

Print the process sequence list.

In the **Priority** list, move the item up.

In the **Priority** list, move the item down.

Move the selected test to the **Priority** list.

Move the selected test to the **Default** list.

Move all tests from the **Priority** to the **Default** list.

Diagnostics

➔ Utilities > Diagnostics

Diagnostics actions are designed for use by Roche representatives or when instructed by them to do so. Therefore, these functions are not described in this manual.

You need at least **Lab Manager** user rights to perform diagnostics functions.

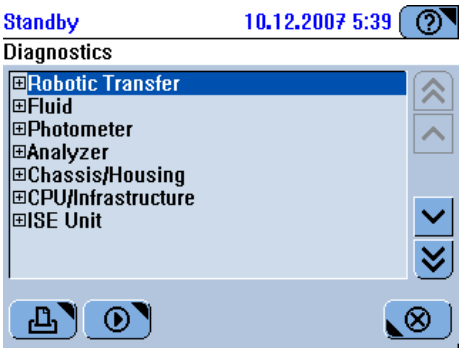


Figure A-80 Diagnostics list

You can choose one of the following options:

- All
- **Selected** (Print the actions of the selected action group.)

With a topic selected: expand or select the list.

With a diagnostic action selected: Perform the selected action.

At the end of performing a diagnostics action (system status transition from **Diagnostics** to **Ready**), the system checks that all modules are initialized, if they are not, initialization is performed.

Inventory

The inventory displays information on all bottle sets that are defined on any of the disks used on this **cobas c** 111 instrument, including sets that were removed from the disk, as long as they were not empty or their expiration date had not passed yet.

(Bottle sets that have been removed from the disk and whose expiration date had passed more than 30 days ago are automatically deleted from the **Inventory** list, provided there is still a valid set for the same fluid on board. If this were not the case, the set that was loaded last would remain in the inventory.)

➔ **Utilities** > **Inventory**

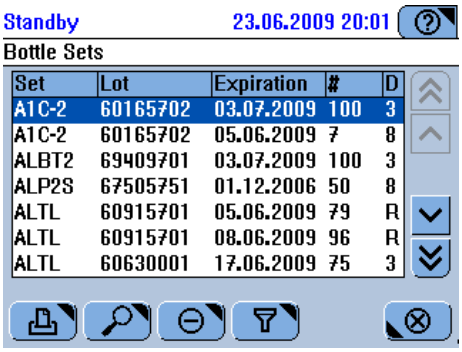


Figure A-81 Bottle set inventory

Print the bottle set list.

You can choose one of the following options:

- **List**
- **Detail of Bottle Set**

Display details on the selected bottle set.

Delete the selected bottle set from the list.

Bottle sets must be removed from the disk before you can delete them from the list.

Apply filter criteria to the **Inventory** list.

You can choose one of the following criteria:

- **All**
- **By ID**

Import

➔ Utilities > Import

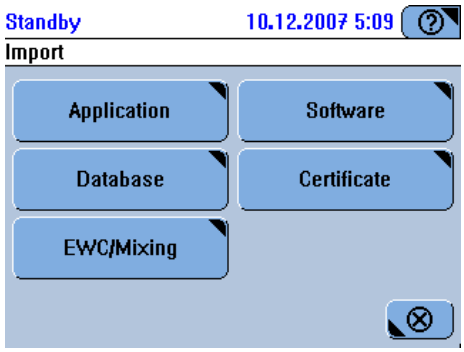


Figure A-82 Importing data

Application Import application data.

Software Import software updates.

Database Import the complete content of the database.

Certificate Import certificates that authenticate reagent barcodes.

EWC/Mixing Import extra wash cycle or mixing information for a particular application.

Users

➔ Utilities > Users

Figure A-83 User administration

There are list items of a lower level. Select the item marked with ⊞ and press ⊞ again to expand the list and display the items.

The list is expanded. Select the item marked with ⊟ and press ⊟ again to hide the items.

Print the user data of the selected user.

With an item selected: change the selected item.

With any other item selected: expand or collapse the list.

Define a new user.

Delete the user.

(You cannot delete your own user data.)

Export

➔ Utilities > Export

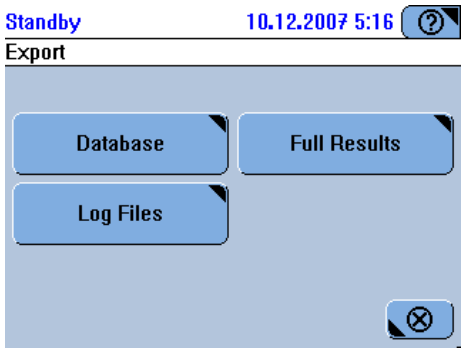


Figure A-84 Exporting data

Database Export the complete content of the database.

Full Results Export the full result data.

Log Files Export the system messages, alarm logs, and possibly trace logs.

Stopping a run

➔ Global action button

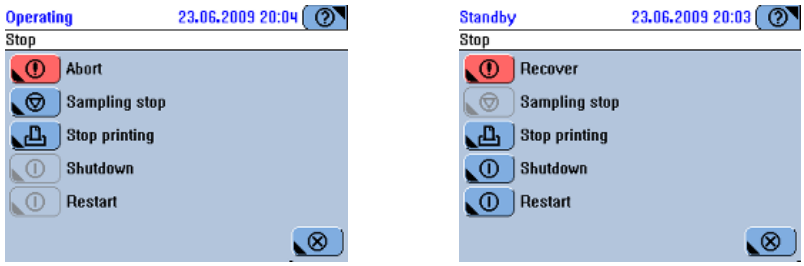


Figure A-85 Stop options

Abort When the system is in **Operating** status: Stop immediately all processing activities.

Pipettings that were not finished are considered not pipetted.

Measurements that have not yet yielded a valid result are considered not measured.

Recover When the system is in **Standby** or **Stopped** status: Initialize all systems and modules that are currently not ready.

Sampling stop Finish the current pipetting action, but do not start a new one.

You can restart processing by pressing .

Stop printing Stop the current printing task. (It may take a few moments before printing actually stops.)

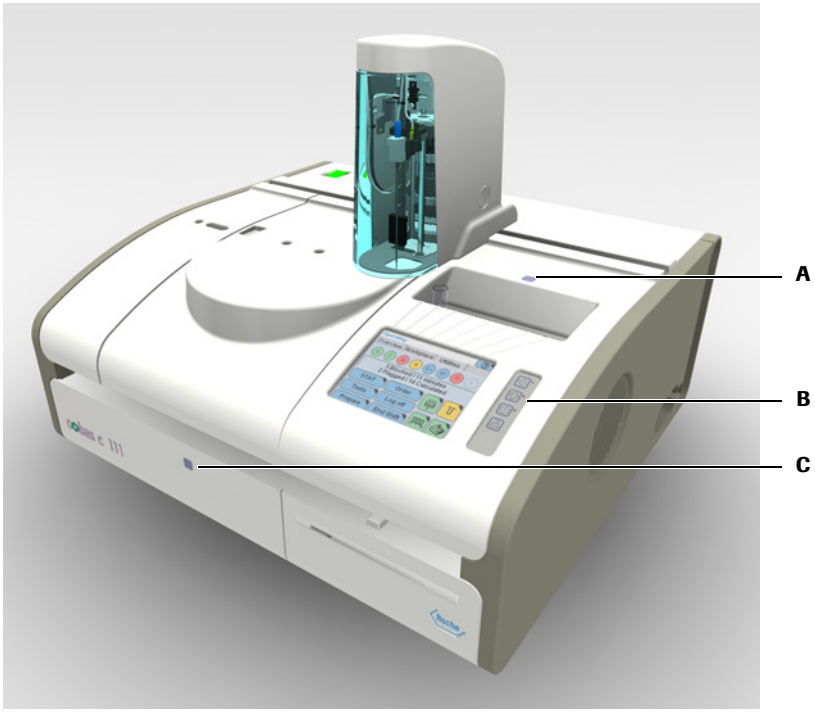
Shutdown Shut down the **cobas c** 111 software and the operating system.

This option is active in **Standby** status only.

Restart Shut down the **cobas c** 111 software and automatically restart it.

This option is active in **Standby** status only. It is used in cases where a configuration change requires restarting the software for it to become effective.

Color interpretation for LEDs



A Sample area LED
B Global button LEDs (from top: Start LED, Stop LED, Alarm LED)
C Main cover LED

Figure A-86 The **cobas c** 111 instrument

The following table lists the LEDs and explains what their colors mean.

LED	Color	Meaning
Main cover LED	Off	No activities in this area. You can open the main cover.
		User intervention is required, for example you are expected to place or remove a bottle.
		The system is performing some action. Do not handle the cover.
	An acoustic signal is sounded when the cover is open while the system is in **Operating** state. You can adjust the volume (**Utilities** > **Configuration** > **System** > **Volume**).	
Sample area LED	Off	No activities in this area. You can remove sample tubes.
		You are expected to place a sample tube.
	Blinking	The transfer head is approaching. Do not place your hand or any object in the sample area.
Start LED	Off	You cannot start the measuring process.
		You can start the measuring process.

Table A-11 LEDs and their meaning

LED	Color	Meaning
Stop LED	Off	Pressing ⊘ does not have any effect.
		Pressing ⊘ leads to the various stop options.
Alarm LED	Off	There are no unconfirmed alarm messages.
		There is at least one unconfirmed alarm message. You need to deal with it as soon as possible.
		There is at least one unconfirmed alarm message. You need to deal with it immediately, processing may not be able to continue unless you do so.
	An acoustic signal is sounded when an alarm is generated. You can adjust the volume (**Utilities** > **Configuration** > **System** > **Volume**).	

Table A-11 LEDs and their meaning

Buttons

The following tables list the buttons used in **cobas c** 111 screens and describe their use. The buttons are grouped according to the kind of function they represent.

General functions

Icon	Name	Use
	Help	Display concise information that is relevant to the current screen and situation.
	Start	Start processing orders.
	Stop	Display Stop options.
	Alarm	Look at alarms.
	Paper Feed	Advance the printer paper.

Table A-12 Global action buttons

Interactive functions

Icon	Name	Use
	Add	Add or define an item.
	Delete	Delete the selected item.
	Cancel	Abort the operation.
	Close	Close the screen.
	Print	Print the content of the current screen's working area.
	List	Display the content of the current screen's working area in a table.
	OK	Confirm the operation, save the data and close the screen.
	Save	
	Detail	Show detailed information on the selected item.
	Filter	Apply filter criteria to the current view.
	Edit	Modify the selected item.
	Perform	Perform the selected action.
	Export	Export data.
	Import	Import data.
	Disk Status	Handle the reagent disk and its reagents. Show the status of the reagents.
	Cuvette Status	Show the status of the cuvette segments. Handle cuvette segments.
	ISE Status	Show the status of ISE electrodes and fluids. Exchange ISE electrodes and fluids.

Table A-13 Interactive buttons

Icon	Name	Use
	System Status	Show the status of the main cover.
	Container Status	Show the status of the external fluid containers. Handle the external fluid containers.
	Temperature Status	Show the status of the reagent cooler and cuvette ring temperature.
	Printer Status	Show the printer status.
	Fan Status	Show whether the sample area fan is running.
	Maintenance Status	Display the maintenance actions list.
	Keyboard	Type information manually.
	Exchange Reagent Disk	Handle the reagent disk.
	Insert Bottle	Place a reagent bottle.
	Remove Bottle	Remove a reagent bottle.
	Mixing	Perform reagent mixing.
	Replace Cuvette	Confirm replacement of the cuvette segment.
	Remove Cuvette	Confirm removal of the cuvette segment.
	Due Calibrations	Select all tests with due calibration or QC.
	Forecast Calibrations	Select all calibrations that are due within the forecast period.
	Default QC	Perform Default QC.
	Interval QC	Perform Interval QC.
	Related Information	Show context information for the result. (Used fluids, together with their lot information.)
	Map Host Codes	Use identical application codes on host and **cobas c** 111 instrument.
	Exchange ISE Bottle	Exchange an ISE fluid bottle.
	Remove ISE Bottle	Remove an ISE fluid bottle.
	Remove Electrode	Remove an ISE electrode.
	Insert Electrode	Insert an ISE electrode.

Table A-13 Interactive buttons (Continued)

Navigation functions

Icon	Name	Use
	Line Up	Move one line up. Select the previous line.
	Line Down	Move one line down. Select the next line.
	Page Up	Move one page up.
	Page Down	Move one page down.
	To Top	Select the first item in a list.
	To Bottom	Select the last item in a list.
	Forward **Next Step**	Open the next screen in a wizard.
	Back **Previous Step**	Open the previous screen in a wizard.

Table A-14 Navigation buttons

Element moving functions

Icon	Name	Use
	Move Up	Move selected element one line up.
	Move Down	Move selected element one line down.
	Move Right	Move selected element to the list on the right.
	Move Left	Move selected element to the list on the left.
	Move All Left	Move all elements in the list to the list on the left.

Table A-15 Element moving buttons

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Daily operation

Performing routine tasks

In this chapter, you will find information on performing the routine tasks that are required for processing orders and keeping the system running.

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Introduction

Daily operation includes the routine tasks that are required to prepare and monitor the system, and to analyze samples.

The screen representations shown in this chapter and throughout this manual are for illustrative purposes only. The screens do not necessarily show valid data.

Safety information

Before you start working with the **cobas c**111 instrument, it is essential that you both read and understand the safety information listed below.

Read carefully all safety notices given in instructions and make sure you understand them.

WARNING

Injury through reagents and other working solutions

Direct contact with reagents, cleaning solutions, or other working solutions may cause personal injury.

When handling reagents, exercise the precautions required for handling laboratory reagents, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Infection by waste solution

Contact with waste solution may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Personal injury or damage to the analyzer due to contact with instrument mechanism

Do not touch moving parts during instrument operation.

Keep all covers closed, operate them as instructed on the screen.

WARNING

Loss of sight

The intense light of the LEDs may severely damage you eyes. Do not stare into the LEDs.

Scanning equipment using LED technology is covered by the international standard IEC 60825-1 LED Safety: Class 1.

Incorrect results or damage to the analyzer due to wrong operation

Operators are required to have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Start all maintenance actions on the screen. Do not perform maintenance actions without the assistance of the user interface.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to a trained service representative.
- Follow standard laboratory practices, especially when working with biohazard material.

Incorrect results or damage to the analyzer due to dust and soiling

The user can leave the main cover open while the system is in **Standby** status or while the instrument is shut down. This can cause dust and dirt being collected in the cuvette ring, which in turn might decrease the quality of the cuvettes.

Keep all covers closed. Open them only to perform operation actions.

Overview

The following table gives an overview of the tasks you might need to perform during daily operation. Roche recommend using the sequence of steps in the way given below; but you may perform the tasks differently. For details on the individual steps, see the relevant sections in this chapter.

	Task	Steps	Navigation	
			With wizard	**As individual steps**
1	Starting the system	1. Switch on the system.		
2	Logging on the system			**Overview** > **Logon**
3	Preparing the system	Start the **Prepare** wizard.	**Overview** > **Prepare**	
		1. Check the external fluid containers.		**Overview** > >
		2. Perform the maintenance actions that are due.		**Utilities** > **Maintenance**
		3. Load the reagent disk.		**Overview** >
		4. Check the reagents.		**Overview** >
		5. Check the cuvettes.		**Overview** >
		6. Perform mixing		**Overview** > > test >
		7. Perform calibrations that are due.		**Workplace** > **Calibrations** > >
4	Defining orders	Start the **Orders** wizard.	**Overview** > **Order** (or **Overview** > **STAT**)	
		1. Identify the sample.		n/a
		2. Select the tests.		n/a
		3. Place the sample.		n/a
		4. Start the run.		
5	Monitoring the progress		n/a	**Overview**
6	Validating results	1. View results.	n/a	**Workplace** > **Result Review**
		2. Handle flagged results.	n/a	**Workplace** > **Result Review** > ... > **Repeat** ... > **Rerun**
		3. Accept results.	n/a	**Workplace** > **Result Review** > > **Accept**

Table B-1 Overview of the daily operation tasks

	Task	Steps	Navigation	
			With wizard	**As individual steps**
7	Performing calibrations			
	Performing individual calibrations	1. Start the wizard.	**Workplace** > **Calibrations** > ⊕	
		2. Select the test.		n/a
		3. Prepare and place the calibrators.		n/a
		4. Start the calibration.		◈
		5. Validate the calibration results.		**Workplace** > **Calibrations** > ✎
		6. Remove the calibrators.		
	Performing all due calibrations	1. Start the wizard.	**Workplace** > **Calibrations** > ⊕	
		2. Select all tests with due calibrations.	⏲	n/a
		or Select all tests with calibration due within the forecast period.	⏲	
		3. Prepare and place the calibrators.		n/a
		4. Start the calibration.		◈
		5. Validate the calibration results.		**Workplace** > **Calibrations** > ✎
		6. Remove the calibrators.		
8	Performing controls			
	Performing **Default QC**	1. Start the wizard.	**Overview** > **Order** > $	
		2. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		3. Start the QC measurement.		◈
		4. Validate the QC results.		**Workplace** > **QC Status** > ✎
		5. Remove the controls.		n/a
	Performing an individual QC measurement	1. Start the wizard.	**Workplace** >	**QC Status** > ⊕
		2. Select a test.		n/a
		3. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		4. Start the QC measurement.		◈
		5. Validate the QC results.		**Workplace** > **QC Status** > ✎
		6. Remove the control.		
	Performing all due QC measurements	1. Start the wizard.	**Overview** > **Order** > $ > ⏲	
		2. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		3. Start the QC measurement.		◈
		4. Validate the QC results.		**Workplace** > **QC Status** > ✎
		5. Remove the controls.		

Table B-1 Overview of the daily operation tasks

	Task	Steps	Navigation	
			With wizard	**As individual steps**
9	Finishing the shift	1. Check for unfinished orders.		**Workplace** > **Orders** Choose > **Not Finished**
		2. Check for non-validated results.		**Workplace** > **Result Review** Choose > **Not Accepted**
		3. Check for non-transmitted results. (If working with a host system only.)		**Workplace** > **Result Review** Choose > **Not Sent to Host**
		4. Start the **End Shift** wizard.	**Overview** > **End Shift**	
		5. Perform the daily backup.		**Utilities** > **Export** > **Database**
		6. Export the full results		**Utilities** > **Export** > **Results**
		7. Clean up the database.		**Workplace** > **Orders** > **Workplace** > **Result Review**> **Workplace** > **QC Status** > **Workplace** > **QC History** > **Workplace** > **Calibrations** >
		8. Perform the maintenance actions that are due.		**Utilities** > **Maintenance**
		9. Replace cuvettes.		**Overview** >
		10. Check the external fluid containers.		**Overview** > >
		11. Remove the reagent disk (if last shift).		**Overview** > >
		12. Log off the system.		**Overview** > button with your user name
		13. Switch off the system (if last shift).	n/a	n/a

Table B-1 Overview of the daily operation tasks

Working with a host system

Communication with the instrument is defined during installation.

For an overview on working with a host system, see *Host connectivity* on page A-33.

Starting the shift

Starting the shift includes the tasks from switching on the instrument up to the moment when you are logged on.

The various tasks are described in the order in which they should be performed.

Switching on the instrument

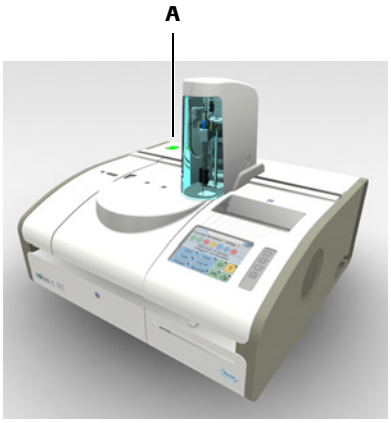
Preconditions

Before you switch on the instrument, make sure the following preconditions are met:

- All covers are closed.
- The external fluid containers are connected.
- The sample area is empty.

► To switch on the instrument

1 Press down **I** on the power toggle switch (A).



The system performs internal checks and routines.

The startup phase may take a few minutes. During this time, a splash screen is displayed.

Do not use the screen until the system is in **Standby** status.

When the system is ready to log on, the **Overview** tab is displayed.

■

Logging on to the system

► To log on the system

1 Press **Log On**.

A screen is displayed for typing your user name.

For information on typing text, see *Typing text* on page A-76.

User name and password are case sensitive. This means that for example User and user are two different names.

2 Type your user name.

Use characters of the alphanumeric keyboard (upper and lower case).

As soon as you type the first characters of your user name, the system looks for a name that starts with these letters and, if it finds one, displays the complete name.

3 Press ⊘.

A screen is displayed for typing your password.

4 Type your password.

Use characters of the alphanumeric keyboard (upper and lower case).

(For security reasons, you cannot see the actual characters when typing.)

5 Press ⊘.

The **Overview** tab is displayed again.

■

Preparing the system

Before you can start analyzing samples, you need to prepare the system. Preparing the system includes both user actions and actions performed automatically by the system, such as heating up the cuvette ring or cooling down the reagent cooler. The process is designed in such a manner that user intervention is mainly required at the beginning and at the end of the **Prepare** phase. This way, the operator does not have to stand by the instrument the whole time.

The easiest way of performing the daily preparation tasks is to follow the **Prepare** wizard.

Preventing intervention during sample processing

Performing conscientiously all preparation steps reduces considerably the chances of you having to intervene during routine operation.

Follow the steps suggested by the wizard

You are guided through the preparation process by the **Prepare** wizard. This sequence of screens shows you which actions you should perform and in which order.

Skipping a step

You may skip a step. Before you do so, remind yourself of the consequences. In many cases, skipping a step simply means postponing the task to a more convenient time. In other cases, skipping a step could prevent the system from performing an analysis; for example if you chose not to replace a reagent that is low, a test that uses this reagent may not have enough reagent.

Short guide

The following table provides an overview of the steps that make up the preparation process.

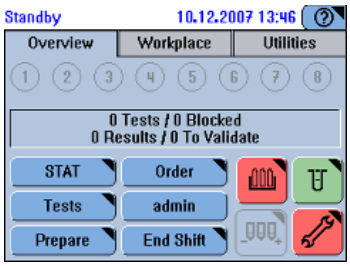
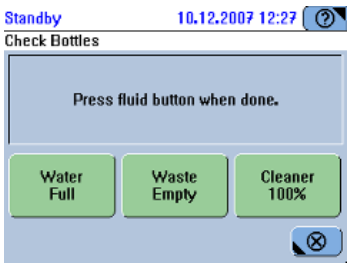
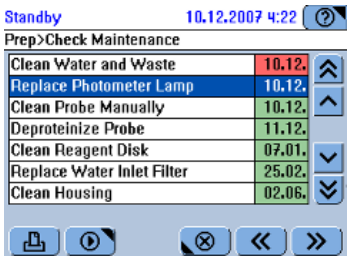
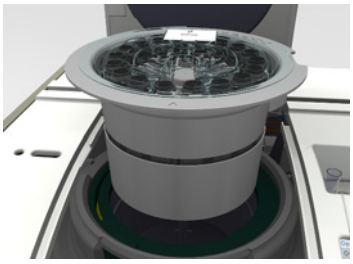
Step		User action
1	Start the Prepare wizard. 	1. On the **Overview** tab, press **Prepare**.
2	Check the status of the external containers. 	1. Refill the water container, if required, and confirm by pressing the water button. (If you refill the water, empty the waste as well.) 2. Empty the waste container, if required, and confirm by pressing the waste button. 3. Replace the cleaner bottle, if required, and confirm by pressing the cleaner button. 4. Press ≫ to proceed to the next stage in the **Prepare** wizard.
3	Perform the maintenance actions that are due. 	1. Check which maintenance actions are due. 2. Perform the maintenance actions. Perform at least all red maintenance actions. 3. Press ≫ to proceed to the next stage in the **Prepare** wizard.
4	Prepare the reagent disk. 	1. Open the main cover. 2. Remove the disk from its container. 3. Place the disk on the instrument. 4. Close the main cover. A screen is displayed, showing the reagent status.

Table B-2 Steps for preparing the system

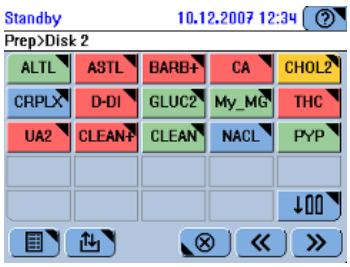
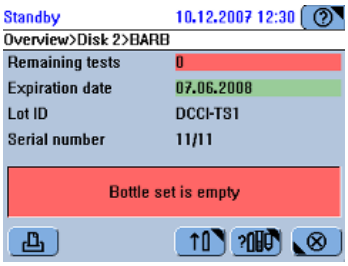
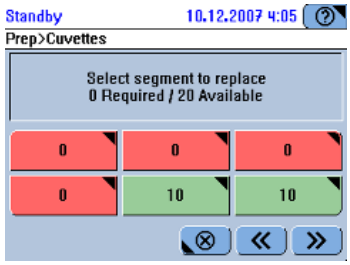
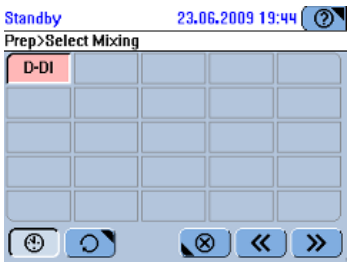
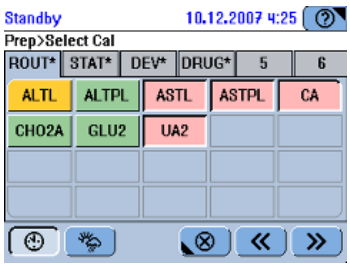
Step		User action
5	Prepare the reagents.  	Deal with at least all red and yellow buttons. 1. Press a reagent button to check the details. Replace the empty reagents. 2. Press ↑. 3. Open the main cover 4. Remove the bottle. 5. Press ✓ to confirm. 6. Remove the remaining bottles of the set. 7. Press ↓. 8. Place the new bottle. 9. Press ✓ to confirm. 10. Load the remaining bottles of the set. 11. Press » to proceed to the next stage in the **Prepare** wizard.
6	Prepare the cuvettes. 	Replace all red cuvette segments. 1. Press the cuvette button. 2. Open the main cover. 3. Replace the cuvette segment. 4. Press ⇵ to confirm the replacement. 5. Replace the remaining segments that need replacing. 6. Press » to proceed to the next stage in the **Prepare** wizard.
7	Perform reagent mixing. 	1. Select the test(s). 2. Press ↻.
8	Perform calibrations. 	Perform the calibrations. 1. Check the test selection. 2. Press ». 3. Place the calibrators. 4. On the placement screen, press ✓. 5. Press ◇. 6. Validate the results.

Table B-2 Steps for preparing the system

Starting the Prepare wizard

► **To start the preparation process**

1 Choose **Overview** > **Prepare**.

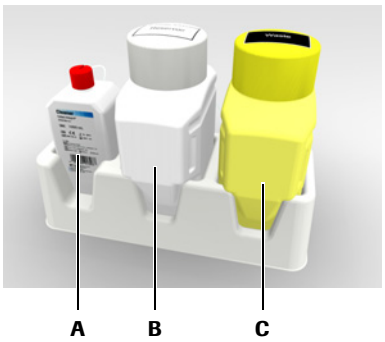
■

Checking the status of the external fluid containers

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Injury through reagents and other working solutions* on page B-5.
- *Infection by biohazardous materials* on page B-5.
- *Infection by waste solution* on page B-5.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page B-5.

The external fluid containers are placed on a rack.



A Cleaner bottle (red cap)
B Water container (white)
C Waste container (yellow)

Figure B-1 External fluid bottles

The status of all three containers is displayed on the same screen:

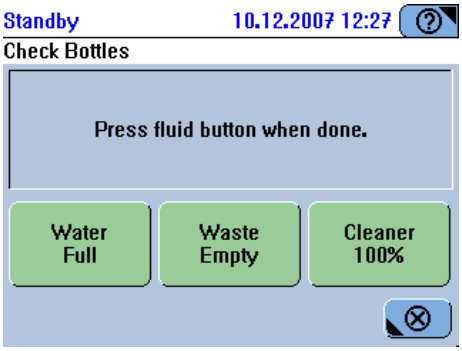


Figure B-2

► To check the water container

1 Check the water button.

	There is no water left. (A fluid sensor detected that there is no water coming from the water container.) You need to refill the water now. No new tests can be processed, started tests may have to be restarted after refill.
	The water container was last filled up more than one day ago. You should check the water level and refill if required.
	No action is required.

The system does not monitor the filling level. It is up to the operator to fill up the water container regularly.

2 Refill the water, if required.

WARNING

Danger of poor measurement quality due to inadequate water quality

Inadequate water quality may lead to incorrect results. Always use purified water of the quality specified in section *Technical specifications*.

- Remove the tubing adapter from the white water container and place it on a clean surface.
- Refill the bottle with purified water.
- Insert the tubing adapter. Press down firmly.

3 On the screen that shows the container status, press the water button to confirm that you have refilled the water.

4 Roche recommend to empty the waste container whenever you refill the water container.

See *To check the waste container* on page B-17.

■

When refilling the water without using the Prepare wizard:

Choose **Overview** > > .

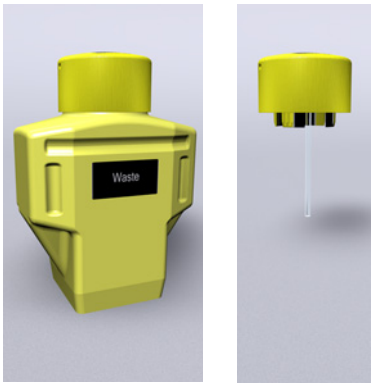
► To check the waste container

1 Check the waste button.

	The waste container was last emptied more than one day ago. You should check the waste level and empty if required.
	No action is required.

The system does not monitor the filling level. It is up to the operator to empty the waste container regularly.

2 Empty the waste container, if required.



- Have the spare waste container ready.

  The system periodically performs wash actions. Therefore, an external waste container must be connected at all times.
- Remove the tubing adapter from the yellow waste container and insert it in the spare container.
- Remove the bottle from the rack and place it on a firm and even surface.
- Place the spare container on the rack.
- Check that the tubing adapter is properly inserted.
- Empty the removed waste container. Treat the fluid as biohazardous waste.
- Rinse the container with water and leave it to dry.

3 On the screen that shows the container status, press the waste button to confirm that you have emptied the container.

■

When emptying the waste without using the Prepare wizard:

Choose **Overview** > > .

► To check the cleaner bottle

1 Check the cleaner button.

	A fluid sensor detected that there is no cleaner in the instrument tubing. You need to replace the cleaner bottle now. No new tests can be processed, started tests may have to be restarted after replacing the bottle.
	The cleaner level is down to 10% or lower. See the % indication.
	No action is required.

2 Replace the cleaner bottle, if required.

- Remove the tubing adapter from the cleaner bottle and place it on a clean noncorrosive surface.
- Dispose of the bottle.
- Remove the cap from the new bottle.
- Place the new bottle on the rack.
- Insert the tubing adapter and press it down firmly.

3 On the screen that shows the container status, press the cleaner button to confirm that you have exchanged the cleaner bottle.

Level monitoring for the cleaner bottle is based on the number of cleaning and pipetting actions that were performed. The counter is reset when you press the cleaner button. Make sure you only press the button when you actually have replaced the bottle.

4 Press [»] to proceed to the next stage in the **Prepare** wizard.

■

When replacing the cleaner bottle without using the Prepare wizard:

Choose **Overview** > [🧪] > [🧪🧪🧪].

Performing maintenance actions

Maintenance actions need to be performed periodically or after certain events.

To ensure the smooth running of the system, you should perform maintenance actions either as part of the preparation or the end of shift activities.

For information on scheduling maintenance actions, see *Scheduling maintenance actions* on page B-158.

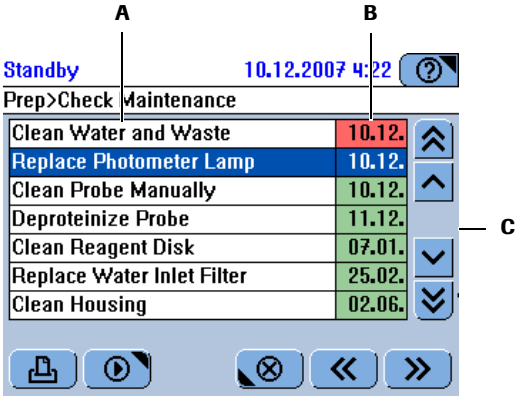
Make sure that you have read and understood section *Safety information* on page C-8.

If you interrupt the performing of a maintenance action that was due, its status will remain due, and you need to fully re-perform the action later.

► To perform maintenance actions

Checking what maintenance actions are due

1 Check the colors of the maintenance actions.



A Maintenance action name.
B Due dates, in ascending order.
C Use the scroll bar to display the maintenance actions that are currently hidden.

Figure B-3

The maintenance actions are sorted by the maintenance date by when they should be performed. Use these dates for planning the maintenance actions, for example for ordering the required materials.

Interpreting the colors

	The defined maintenance interval has expired. Perform this maintenance action now. The system may not be able to operate until this action is performed.
	This maintenance action should be performed on the next major maintenance day.
	No action is currently required.
	This maintenance action is selected.

Performing the maintenance actions

2 Select the maintenance action you want to perform.

The selected line turns blue.

WARNING

Incorrect results or processing stop due to skipping maintenance actions

Not performing maintenance actions that are due may lead to situations where the system cannot continue processing orders, or it may lead to incorrect results. If at all possible, perform the maintenance actions when they are due.

3 Press ⓘ.

The maintenance definition screen is displayed.

For information on how to perform individual maintenance actions, see Chapter 8 *General maintenance*.

4 Press ✓ to start the action.

5 Follow the instructions on the screen.

6 Perform the next maintenance action that is due.

7 When you have finished performing maintenance actions, press » to proceed to the next stage in the wizard.

■

When performing maintenance actions without using the Prepare wizard:

Choose **Utilities** > **Maintenance**.

Preparing the reagent disk

The reagent disk holds the reagent and diluent bottles. During periods when you are not performing tests, for example at night or during holidays, the disk is placed in a reagent disk container and stored in a refrigerated place. Reagents should be stored at temperatures in the range of 2 to 8°C.

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Injury through reagents and other working solutions* on page B-5.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page B-5.

CAUTION

Spillage through tipping reagent disk

The reagent disk container can slip off or tip over if it is not placed on an even horizontal surface.

When storing the reagent disk container, make sure to place it on a firm, even, horizontal surface that is easily accessible.

When handling the reagent disk, make sure not to tilt it.

► To load the reagent disk

1. Get the reagent disk from the refrigerator and remove it from its container.
2. Open the main cover.

   A screen is displayed, asking you to insert the disk.
3. Place the reagent disk in the reagent cooler.

   Make sure the reagent port faces the front and align the cut-outs with their counterparts on the reagent cooler.

   The system automatically detects that a disk was inserted.

   A screen is displayed, asking you to close the main cover.
4. Close the main cover.

   At this stage, the system identifies the disk.

   A screen is displayed that shows the status of the reagent sets.

■

When handling the reagent disk without using the Prepare wizard:

Choose **Overview** > .

Preparing the reagents

Reagents are handled in sets. A set consists of up to three reagents. If for example one reagent bottle of a set is empty, all reagents of the set need to be replaced. The system only uses reagents of complete sets.

On the screen, each set is represented by a separate button.

Use reagents of the same lot, if possible

When replacing a new reagent set, try to use one of the same lot as the old one. This way you avoid having to perform a calibration.

Diluent and cleaner bottles

An extra diluent or cleaner bottle is considered one set. Extra cleaners and diluents are handled in the same type of bottles that are used for reagents. Their handling works the same way. In the following, the process is described for reagents.

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Injury through reagents and other working solutions* on page B-5.
- *Infection by biohazardous materials* on page B-5.
- *Loss of sight* on page B-6.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page B-5.

WARNING

Incorrect results due to declining reagent quality

Due to the declining quality of reagents, the quality of measurement may decline. This may cause incorrect results.

Make sure to use reagents whose expiration date has not passed yet.

Incorrect results due to reagent dilution through condensation

In ambient conditions of high temperature and humidity, condensation can build up inside the reagent bottles. This leads to dilution of the reagent.

In such conditions and when not performing tests, especially if you observe condensation on the reagent disk or in the reagent cooler, be sure to remove the reagent disk from the instrument and place it in the reagent disk container. Close the container with its lid and place it in a refrigerator.

Incorrect results due to condensation in the reagent cooler

In ambient conditions of high temperature and humidity, condensation can build up in the reagent cooler. Water can spill on the analyzer unit and get into the cuvettes when removing the reagent disk.

In ambient conditions of high temperature and humidity, be sure to periodically wipe up the condensation water in the reagent cooler.

Incorrect results due to inappropriate reagent handling

Removing and loading reagents while the reagent disk is outside the instrument may lead to inconsistencies between the recorded and the physically loaded reagents and consequently to incorrect results.

Always remove and load reagents while the reagent disk is on the instrument and by using the software supported procedures.

NOTICE

Damage to the reagent disk

The reagent disk is designed to handle reagents while it is loaded on the instrument. The cover is equipped with a locking mechanism.

Always remove and load reagents while the reagent disk is on the instrument and by using the software supported procedures.

Checking the status of reagent sets

There are two main ways of checking the status of reagent sets:

- To get a general overview of the status of all reagents that are defined on any disk, use **Utilities** > **Inventory**.

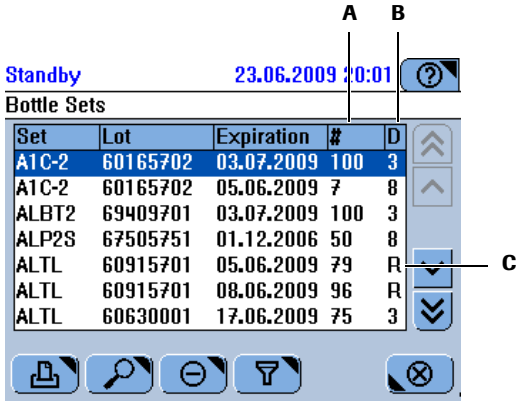
  For information on deleting reagent sets from the **Inventory** list, see *Deleting bottle sets from the Inventory list* on page B-120.

- To check the status of individual reagent sets, use **Overview** > **Tests** > test icon.

► To gain a general overview of the currently defined reagent sets

1 Choose **Utilities** > **Inventory**.

The **Bottle sets** list is displayed. It contains all bottle sets that are defined on any of the disks used on this **cobas c** 111 instrument, including sets that were removed from the disk, as long as they were not empty or their expiration date has not passed yet.



A Number of tests left

B ID of reagent disk on which the set is defined

C **R** indicates that the set was removed from the disk.

Figure B-4

2 Select a set and press .

A dialog box is displayed that contains detailed set information.

3 Press .

A dialog box is displayed that contains set, calibration, and QC information.

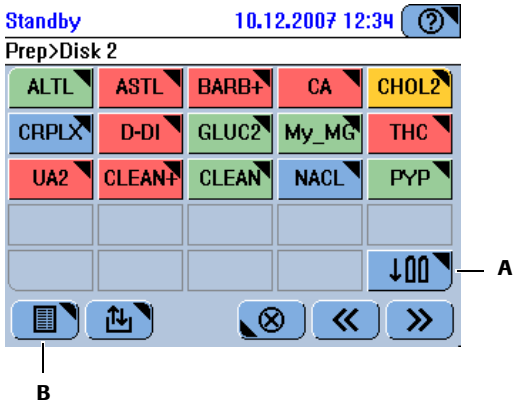
4 Press to close the dialog boxes until the **Utilities** tab is displayed.

■

► To check the status of individual reagent sets

1 Choose **Overview** > .

2 Check the colors of the reagent set buttons.



A Press to add a reagent set. **B** Press to display the disk content in a table.

Figure B-5

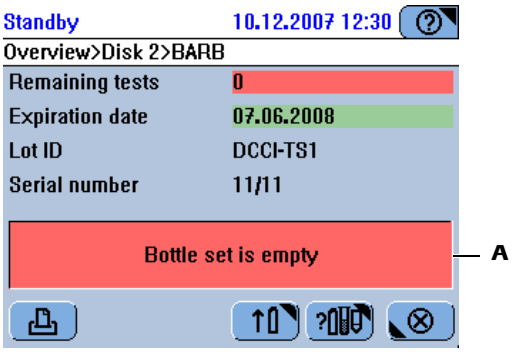
Interpreting the colors

Color	Meaning	Possible actions
	No tests can be performed with this reagent set.	
	The number of available tests is 0.	Replace the reagent set.
	The set is incomplete.	Add the missing reagent.
	The test needs calibrating.	Perform calibration.
	There are fewer than 10% of tests left for this set.	Load a new reagent set as soon as possible.
	The expiration date has passed.	
	A QC is due or its result has not been accepted.	Perform QC as soon as possible or accept the result
	A more recent version of the application has been imported.	Install the new version of the application to start working with it.
	This development channel test is run without extra wash cycles.	Activate the extra wash cycle. Roche strongly recommends to always use extra wash cycles with development channel applications and also to always load extra cleaner when tests with extra wash cycles are used.
	Ready for use.	No action is currently required.
	There is no application that uses this reagent set.	Add the missing application.
	A required diluent or cleaner is not on board.	Load the missing fluid.

Displaying detailed information on a reagent set

3 Press a reagent button.

A screen is displayed that shows the details of the selected reagent.



A Status description

Figure B-6

■

Preparing reagents

During preparation, you typically replace reagents that are empty or whose expiration date has passed, or you add new reagents.

WARNING

Incorrect results due to impurities and carryover

Traces of analytes or reagents may be carried over one test to the next when reusing bottle caps.

Do not remove reagent bottles that are not empty with the purpose of loading them again later.

► To prepare the reagents

1 Choose **Overview** > **Tests**.

Preparing the reagent set

2 Obtain the reagent sets you want do add or replace.

When replacing a reagent set, try to use one of the same lot as the old one. (This way, if you work with the calibration sequence **Each Lot and Interval**, you avoid having to perform a calibration.)

Removing a reagent set

3 Select the reagent you want to remove.

4 Press ⇑.

The system moves the first bottle of the set to the reagent port.

5 Wait for the main cover LED to turn green.

A message is displayed, asking you to open the main cover and remove the bottle.

6 Open the main cover and remove the bottle.

7 Press ⓥ to confirm the removal.

The system does not check whether you have actually removed the bottle.

8 Do one of the following:

If	Do this
There is another bottle belonging to the set:	The system moves this bottle to the reagent port. A screen is displayed, asking you to remove the bottle. 1. Remove the bottle. 2. Press ⓥ to confirm the removal. 3. Start adding the new reagent set.
All bottles of the set are removed:	1. Start adding the new reagent set.

The screen with the reagent set buttons is displayed again. The button for the removed set is no longer present. If you did not remove all bottles of the set, the reagent set would be disabled, its button would be red.

Adding a reagent set

9 Open the main cover if required.

10 Press ↓▯▯.

A screen is displayed, asking you to scan the bottle barcode.

11 Scan the barcode on the bottle.

When scanning, bear this in mind:

- Scanning its barcode is the only way of identifying a reagent, diluent, and cleaner bottle.
- If there are not enough free slots for all bottles of the set, a message will inform you.
- You cannot re-insert empty bottles that were previously removed from the system. If you scanned such bottle, a message would inform you that you cannot do this.

A screen is displayed, asking you to place the bottle on the reagent disk.

Time limit for placing reagent bottles

- The system assumes that you place the bottle that you just scanned.
- You need to place the reagent bottle on the reagent disk within 15 seconds of scanning the reagent barcode. Failing to confirm the placement within 15 seconds cancels the current identification process. You will be asked to scan the bottle again.

WARNING

Incorrect results due to not placing the identified reagent

The system assumes that the operator places the reagent that was just identified. Failing to do so might lead to wrong results.

12 Remove the cap from the bottle and place it in the reagent bay.

13 Press ✓ to confirm the insertion.

If you confirm without placing the bottle, the system assumes that the bottle is placed.

If you press ⊗ after placing the bottle, the position is deemed empty.

When the first reagent bottle is loaded, the reagent set is defined. From this moment on, the reagents are handled as part of the set. You no longer handle them as individual reagents.

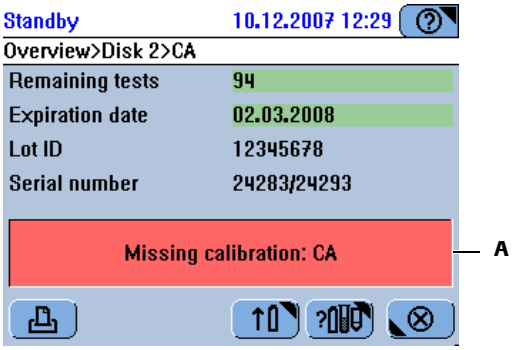
14 Do one of the following:

If	Do this
There is another bottle belonging to the set:	A screen is displayed, asking you to scan the bottle. 1. Scan the bottle 2. Insert the bottle. 3. Press ✓ to confirm the insertion.
All bottles of the set are inserted:	1. Close the main cover. On the screen with the reagent set buttons, the button for the new set is now present.

15 On the screen with the reagent set buttons, press the button for the set you just inserted.

A screen is displayed that shows details of the set.

The status description points to the action you need to take. If you just inserted a reagent set, you may have to perform the initial calibration and QC.



A Status description

Figure B-7

16 Press ⊗.

17 When you have finished adding and replacing reagent sets, press » to proceed to the next stage in the **Prepare** wizard.

■

When handling the reagent sets without using the Prepare wizard:
Choose **Overview** > .

Preparing cuvettes

Cuvettes are supplied and handled in cuvette segments. Each segment contains ten cuvettes. The segments are placed on the cuvette ring of the rotor.

For information on cuvette segments, see *Cuvette segments* on page A-55.
For information on the cuvette ring, see *Cuvette ring* on page A-60.

Each segment on the cuvette ring is represented by a button on the screen.

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

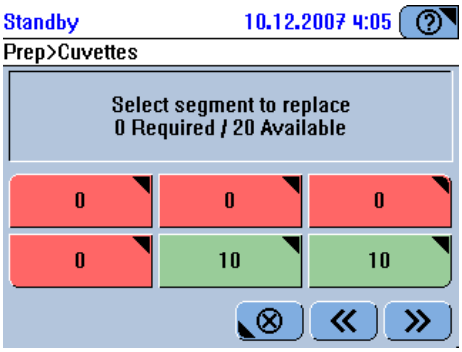
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page B-5.
- *Infection by waste solution* on page B-5.

► To prepare the cuvettes

Checking the cuvette status

1 Check the color of the cuvette segment buttons.

You can refresh the cuvette screen by pressing . (If there were pending orders, this would also start their processing.)



Interpreting the screen

The number in the button indicates how many cuvettes are free to be used.

Icon	Meaning	Possible actions
	All cuvettes are used.	Replace the segment.
	Up to two cuvettes are free to be used.	
	More than two cuvettes are free to be used.	No action is currently required.

Replacing cuvette segments

2 Press a segment button.

A screen is displayed, informing you that the system is ready for cuvette handling.

3 Wait for the main cover LED to turn green.

4 Open the main cover.

5 Remove the segment and treat it as biohazardous waste.

Incorrect results due to scratched or soiled cuvettes

Scratches and impurities on the cuvettes distort the measurements.

Do not touch the cuvettes and make sure they do not touch other items when handling them.

6 Insert a new cuvette segment.

7 Press ⇵U to confirm the replacement.

(Press ↑U if you removed the segment without replacing it.)

8 Do one of the following:

If	Do this
You want to exchange another segment:	Perform steps 2 through 7.
This was the last segment you wanted to exchange:	Close the main cover.

9 When you have finished replacing cuvettes, press » to proceed to the next stage in the **Prepare** wizard.

■

When handling cuvette segments without using the Prepare wizard:

Choose **Overview** > U. The system must be in **Standby** status.

Performing reagent mixing

Reagents that contain Latex granules, for example D-Dimer, require periodic mixing. The mixing interval is part of the application definitions and cannot be changed or deleted by the user. The system checks every 30 minutes for reagent sets that require mixing.

Within the **Prepare** phase a screen is displayed that lists all reagent sets for which a mixing interval is defined.

► To perform the mixing

1 Select the reagent sets you want to mix.

If working with the **Prepare** wizard, the reagent sets that need mixing are automatically selected.

2 Press ⟲.

Mixing starts. A screen is displayed informing you about the progress of the mixing action.

(If there is more than one bottle in the set with a mixing interval defined, it will be mixed as well, irrespective of being due or not.)

3 When mixing is finished, press ⊗ to close the screen.

4 Press » to proceed to the next stage in the **Prepare** wizard.

■

When mixing reagents without using the Prepare wizard:

Choose **Overview** > . Press the reagent set button and then . The system must be in **Standby** status.

Performing the calibrations (Prepare phase)

At this stage, the system checks for all calibrations that are due.

For an overview on calibration, see *Calibration* on page A-26.
For performing individual calibrations, see *Performing calibrations* on page B-59.

By default, all calibrations that are due or will be due within the forecast period are taken into account during the **Prepare** phase.

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Injury through reagents and other working solutions* on page B-5.
- *Infection by biohazardous materials* on page B-5.

WARNING

Skin inflammation caused by reagents

Direct contact with reagents may cause skin irritation, inflammation, or burns.

When handling reagents, be sure to wear protective equipment and observe the cautions given in the package insert.

Incorrect results due to expired calibration

Calibrations are performed to compensate for changes over time in reagents and in the measurement systems. Failing to perform calibrations when they are due may lead to incorrect results.

Make sure to perform calibrations when they are due.

Incorrect results due to wrong tube placement

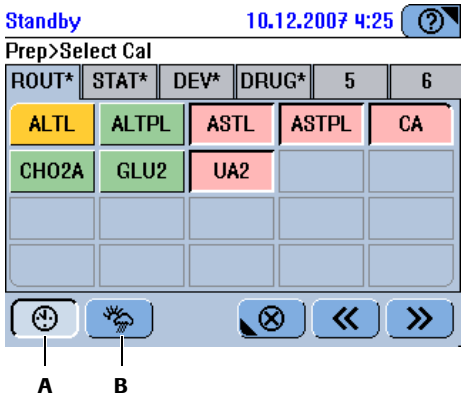
Be sure to place the calibrators in the specified positions.

► To perform the calibrations

A screen is displayed that shows all active tests.

Checking which calibrations are due

1 Check the colors of the test buttons.



A Press to cancel the selection of all tests that need calibrating

B Press to cancel the selection of all tests that need calibrating within the forecast period.

Figure B-8

Interpreting the colors

Color	Meaning	Possible actions
	No sample tests can be measured. Possible reasons:	
	Initial calibration is required.	Perform the calibration.
	The calibration failed.	Check the flag to find out why the calibration failed. Repeat the calibration if necessary.
	The calibration was successfully performed, but its results have not been accepted yet.	Validate the calibration results.
	QC is due.	Perform QC as soon as possible.
	The calibration is OK. Its results have been accepted.	No action is currently required.
	The calibration is OK. It applies to a reagent set that is not active.	No action is currently required.

Modifying selections

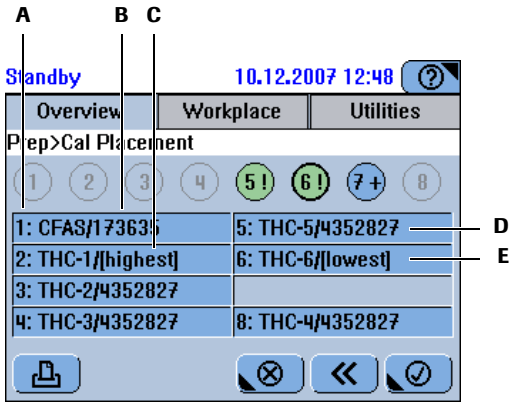
By default, all tests whose calibration is due or will be due within the forecast period are automatically selected. You can cancel these selections by pressing , or a test button.

If you do not perform a calibration that is due, the affected test is blocked; you cannot perform this test.

Performing calibrations

2 On the screen that shows the tests, press [»].

A screen is displayed that lists all required calibrators, and it shows on which position to place them.



A Position on the sample area where to place the calibrator.
B Lot number
C Calibrator with highest concentration
D There are not enough empty positions, the system suggests using occupied positions.
E Calibrator with lowest concentration

Figure B-9

- The system first uses the free positions, if there are not enough free positions, occupied positions are suggested. For these you would have to replace the currently loaded tubes with calibrator tubes.
- With absorbance tests that require several calibrators, the calibrators are placed according to their concentration, starting with the highest concentration.

Calibrators with several concentrations are listed according to their concentration, starting with the one with the highest concentration. They are displayed as follows:

Number of calibrators	Displayed information
1	Position, name, lot number
2	1. Position, name, **highest** 2. Position, name, lot number
More than 2	1. Position, name, **highest** 2. Position, name, lot number 3. … 4. Position, name, **lowest**

3 Prepare the calibrators.

4 Place the calibrators on the sample area positions indicated on the placement list.

5 Press [✓] to confirm the placement.

6 Press [◇] to start the calibration.

7 Choose **Workplace** > **Calibrations** to check the status of the calibrations.

Validating the results

8 Validate the results.

See *Validating calibration results* on page B-64.

■

When performing calibrations without using the Prepare wizard:
Choose **Workplace** > **Calibrations** > ⊕.

*End of **Prepare** phase*

The instrument is now ready for analyzing samples.

You may want to perform QC before analyzing samples.

See *Performing QC* on page B-68.

Analyzing samples

Safety information

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Infection by biohazardous materials* on page B-5.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page B-5.
- *Loss of sight* on page B-6.

WARNING

Incorrect results due to inadequate sample preparation

Specimen containing clots may obstruct the probe. Specimen containing bubbles or foam may cause level detection errors and air pipetting. Consequently, incorrect results may be generated.

Take adequate care when preparing the samples.

Incorrect results due to insufficient fluid

Insufficient fluid may lead to inaccurate pipetting and consequently to incorrect results.

Always fill the tubes with enough fluid that at least the defined dead volume of fluid is left when pipetting is complete.

See *Tubes* on page A-54.

Time limit for placing samples

The system assumes that you place the sample tube that you just identified.

You need to place the sample on the sample area within 10 seconds of confirming the test selection. Failing to place the sample tube within 10 seconds cancels the current identification process. You will be asked to identify the sample tube again.

Short guide

The following table gives an overview of the tasks you typically perform when analyzing samples.

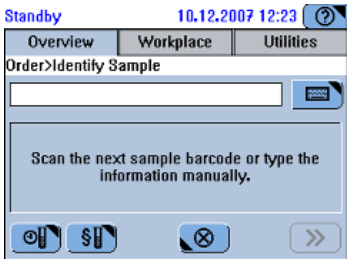
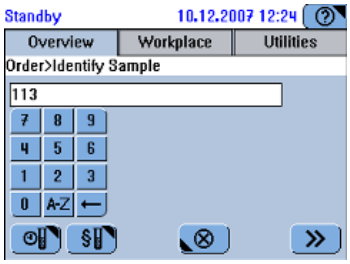
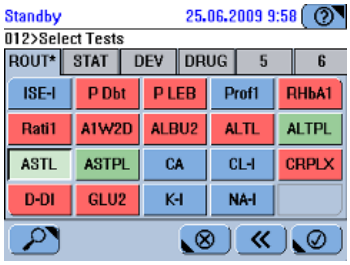
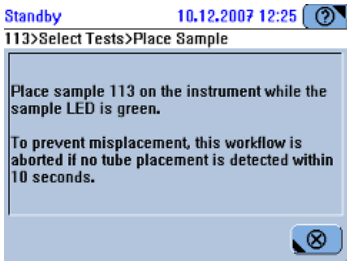
Step		User action
1	Identify the sample.		If working with sample barcodes: 1. Scan the barcode using the barcode scanner.
			If working without sample barcodes, type the sample ID by using the screen keyboards. 1. Press ⌨. 2. Type the ID. 3. Press ».
2	Select the tests, ratios and profiles. This step is not required if the workflow setting **Working Mode** is **Host**. (**Utilities** > **Configuration** > **Workflow**.)		1. Press a tab to select the test panel (if required). 2. Press an active test, ratio or profile to select it. Press a selected item to cancel its selection. 3. Press ».
3	Place the sample.		1. Place the sample on any free position on the sample area. You need to place the sample within 10 seconds of pressing ». Failing to place the sample tube within 10 seconds cancels the current identification process. You will again be asked to identify the sample tube.
4	Start processing.		Press ◈.

Table B-3 Steps for analyzing samples

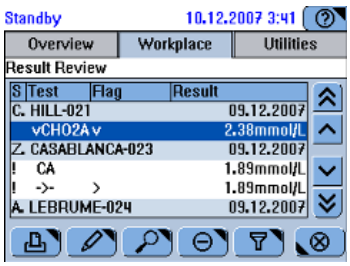
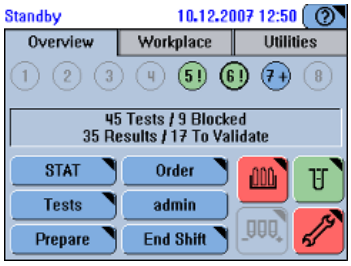
Step		User action
5 Validate the results.		1. Choose **Workplace** > **Results**. 2. Validate the result (You can accept the result or perform the test again.)
6 Remove the samples.		1. Press the **Overview** tab. 2. Check the status of the sample tube button that corresponds to the sample you want to remove. 3. If the sample tube button is green, remove the tube.

Table B-3 Steps for analyzing samples

System setup and order definition workflow

The workflow for defining orders depends on a few configuration settings:

➔ **Utilities** > **Configuration** > **Workflow**

Working Mode The **Working Mode** defines the way you select tests when defining orders.

- Use **Manual** if you use the **cobas c** 111 instrument as a stand-alone system.

  During order definition, the test selection screen is displayed, allowing you to select the tests or to make changes to the selection.

- Use **Host** if the **cobas c** 111 instrument is connected to a host computer or to a computer running the **cobas c** 111 Printer Tool.

  The orders are automatically defined, the test selection screen is not displayed. After identifying the sample, you are asked to place the sample.

Sample Barcode Use **On** if you exclusively work with barcoded sample tubes. When defining orders, the screen for typing the sample ID manually is skipped.

Order Mode The order mode reflects the way in which you organize the tests on the test selection screen.

Use **Easy** if the reagents fit on one or two reagent disks and you work with one test panel on the screen (You can fit up to 25 tests and profiles on this panel).

Use **Full** if you distribute the reagents across several (up to eight) reagent disks and if you predominantly work with specific groups of tests, for example for emergency situations or for testing diabetes. You can define up to 20 tests and profiles on each panel (tab).

See *Assigning tests to test tabs* on page B-119.

Sample ID Handling The *sample ID* is an identifier of up to 23 alphanumeric characters that is unique within a whole organization, for example the hospital. It cannot be changed once the order is saved. This ID is used for communication with a laboratory information system.

The *order ID* is an identifier of up to 23 alphanumeric characters that is unique within the laboratory. In practice, this could for example be an autonumber followed by the patient name.

Because there is limited space when displaying lists on screen, Roche recommend to limit the IDs to 13 characters.

If you work with one ID only, the sample ID is used as the order ID as well. There exists a fixed relation between the sample and order IDs. Make sure this ID is unique within the **cobas c** 111 instrument.

- Use **Order ID = Sample ID** to have the system automatically define the order ID identical to the sample ID.
- Use **Independent IDs** to define the sample and order IDs independently of each other.
- Use **Grouped Sample ID** to use identical order and sample IDs as a constant part of any order for a give sample, and to let the system automatically append a running number to the ID for each order.

Auto Order-ID Use **On** to automatically increment the order ID number by one whenever you define a new order. (You only need to define the number of the first order of your shift.)

If you use **On** for this feature, use **Off** for **Order ID = Sample ID**.

Defining orders

Preconditions

- All preparation tasks are complete.
- The required tests are installed on the system and ready for use (calibration and QC performed).
- The system status is either **Standby** or **Operating**.
- At least one sample position on the sample area is free.

- There can be only one order per test and sample.
- Possible post-dilution is predefined in the application definition.

WARNING

Incorrect results due to declining sample quality

Evaporation of sample fluid may lead to incorrect results. In ambient temperatures of more than 25°C, be sure to start processing immediately after placing the sample and defining the order. When processing of the order is finished, be sure to immediately remove the sample from the sample area.

WARNING

Incorrect results due to insufficient fluid

Insufficient fluid may lead to inaccurate pipetting and consequently to incorrect results.

Always fill the tubes with enough fluid that at least the defined dead volume of fluid is left when pipetting is complete.

See *Tubes* on page A-54.

Incorrect results due to inappropriate tube and cup placement

Inappropriate tube and cup placement may lead to inaccurate pipetting and consequently to incorrect results.

Make sure that the primary tubes are placed centrally and perfectly vertically in the holders in the sample area and that they are inserted firmly.

Make sure that secondary tubes are placed centrally on the primary tubes and that they rest fully on them.

NOTICE

Probe damage and instrument malfunction due to not removing primary tube caps

The probe is not designed to pierce tube caps. It can get damaged when trying to pierce tube caps, which can lead to instrument malfunction.

Always remove the caps of primary tubes before placing them on the instrument.

Defining routine orders

► To define an order

1 Choose **Overview** > **Order**.

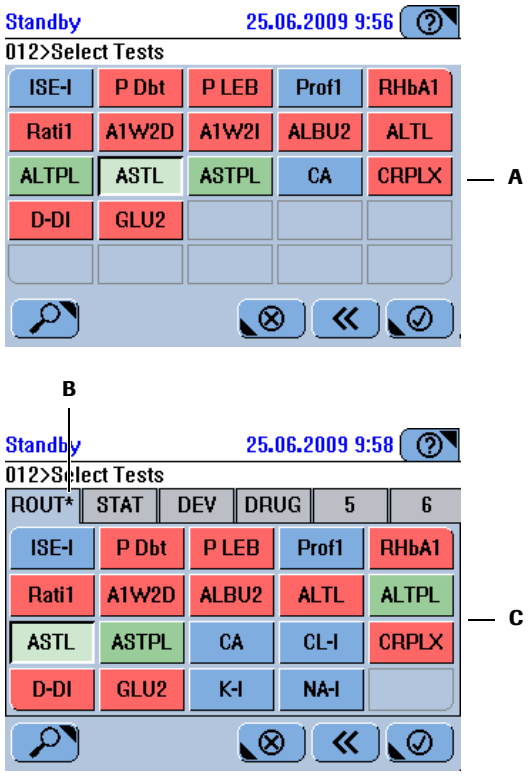
A screen is displayed, asking you to identify the sample.

2 Identify the sample. Do one of the following:

If	Do this
You work with sample barcodes:	Use the barcode scanner to scan the barcode.
You do not work with sample barcodes or if the barcode could not be read for some reason:	1. Press ⌨. 2. Type the sample ID, then press ». 3. Type the order ID, then press ». Note: This step is only required if the configuration setting **Order ID = Sample ID** is not selected.

A screen is displayed that shows all active tests, profiles, and ratios. Note that all applications of a profile or ratio must be installed for it to be active.

(If the workflow setting **Working Mode** is **Host**, this screen will not be displayed. **Utilities** > **Configuration** > **Workflow**.)



A **Easy** mode test-board, all tests fit on one screen.

B Tabs marked with an asterisk contain selected tests.

C **Full** mode test-board. The tests are distributed across several panels (tabs).

Figure B-10

Interpreting the colors

	The test is blocked for one of the following reasons: • The calibration failed. • Initial calibration is required. • For the reagent set, the number of available tests is 0, or a reagent bottle is missing (incomplete reagent set).
	The expiration date of the test has passed. There are only few tests left. A QC is due or its result has not been accepted. A more recent version of the application has been imported. For a development channel: An extra wash cycle is missing.
	The test is on board and ready for use.
	The test is defined but not on board. A required diluent or cleaner is not on board.

The tests are sorted alphabetically. Profiles precede the tests. Profiles display the color of their tests.

3 Select one or several of the tests, profiles, and ratios.

You can select items from more than one tab. (An item can be contained in more than one tab. If it is selected in one, it will automatically be selected in the others.)

Tabs with selected items are marked with an asterisk (*).

4 Press ⓥ to confirm your selection.

5 Wait for the Sample Area LED to turn green. (Make sure to keep clear of the sample area while the LED is yellow and blinking.)

A screen is displayed, asking you to place the sample on the instrument.

6 Place the sample on any free position on the sample area.

Time limit for placing samples

You need to place the sample on the sample area within 10 seconds of confirming the test selection. Failing to place the sample tube within 10 seconds cancels the current identification process. You will be asked to identify the sample tube again.

WARNING

Incorrect results due to not placing the identified sample

The system assumes that the operator places the sample that was just identified. Failing to do so might lead to wrong results.

The system registers where you placed the sample and associates this position with the order you just defined.

The screen for identifying samples is displayed again. You can now start defining the next order. (If there were no free sample positions, the screen for selecting the tests would be displayed instead.)

7 Do one of the following:

If	Do this
There is another order to be defined:	Identify the sample and repeat the order definition process.
There are no more orders to define:	Press ⓧ to close the screen.

8 Press the ◈ global action button to start processing.

See *Starting the run* on page B-44.

If you defined the order while the system was processing orders, new orders will automatically be processed, without pressing ◈.

■

- Roche strongly recommends to always load extra cleaner when tests with extra wash cycles are used.
- Roche Diagnostics Ltd. assumes only limited liability when using the **cobas c** 111 instrument in conjunction with the **cobas c** 111 Development Channel Programming Software. For detailed information on this matter refer to the latest version of the Development Channel Registration Form **cobas c** 111 and the **cobas c** 111 Development Channel Operator's Manual.

Order of processing

When you first start processing orders, the order of the sample placed on the leftmost position on the sample area is processed first. The others follow in sequence from left to right. Once processing is in progress, the orders are processed according to the sequence in which they were defined.

Repeats and reruns of routine orders are performed before routine orders.

See *Repeating tests* on page B-55.
See *Rerunning tests* on page B-56.

Defining STAT orders

Short turn around time (STAT) orders are defined in the same way as routine orders.

► To define a STAT order

1 On the **Overview** tab, press **STAT**.

2 Continue as if defining a routine order.

See *Defining routine orders* on page B-39.

If there is no space on the sample area

Remove any sample whose tube button is green 🟢.

■

Order of processing

When you have defined a STAT order and started the run, the system reacts as follows:

- Existing STAT orders are finished first.
- Started tests of routine orders are finished.
- Repeats and reruns of STAT orders are treated as normal STAT orders. (The order that was defined first will be performed first.)
- Repeats and reruns of routine orders are performed before routine orders.

Recognizing STAT orders on the screens

On the **Overview** tab, the sample buttons for STAT orders are marked with a wide edge.

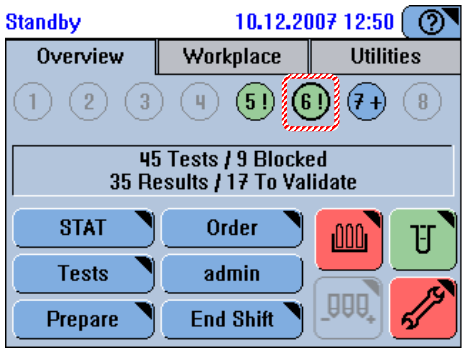


Figure B-11 Example of STAT order icon

In the orders list (**Workplace** > **Orders**), STAT orders are marked with an asterisk (*).

Making changes to an order

You can make changes to orders that either have not yet been processed or that are fully processed. (You can add further tests to an order any time.)

The process of changing an order depends on whether the sample tube is still on the instrument or not.

Making a change to an order when the sample tube is no longer on the sample area is basically the same as defining a new order.

► To change an order

1 Identify the sample.

If the sample is still on the instrument

- On the **Overview** tab, press the sample tube button of the order you want to change.

  A screen is displayed, that shows details on the order and the sample.

- Press ⊕.

  A screen for selecting tests is displayed.

If the sample is no longer on the instrument

- Do one of the following:

If the Starting point was	Perform these steps
Overview > **Order**	A screen is displayed, asking you to scan the sample or to type its ID manually. 1. Identify the sample either by scanning its barcode or by typing the sample ID. If the same barcode was scanned before (during the current day) or you use the same sample ID as in the original order, the system recognizes the original order and displays its associated information. 2. Press [»]. A screen for selecting tests is displayed.
Workplace > **Orders**	A screen is displayed that lists all orders. 1. Select the order you want to change. 2. Press [✎]. A screen for selecting tests is displayed.

2 Select the tests.

- Press an available test to select it.
- Press a selected test to cancel its selection. (Tests that are already scheduled to be performed cannot be cancelled.)

3 Press [✓] to confirm your selection.

If the sample is still on the instrument

A message is displayed showing the position the sample is placed on.

- Press [✓] to confirm the position

  The screen with details on the order and the sample is displayed again.

- Press [⊗] to close the screen.

If the sample is no longer on the instrument

A message is displayed, asking you to place the sample.

- Place the sample on the sample area.

  The orders list is displayed again.

4 The system reschedules the order and processes it as normal.

■

Starting the run

► To start processing an order

1 Press the global action button.

The system checks whether there are enough cuvettes and whether all required reagents are on the reagent disk.

If any of this is not the case, a screen is displayed informing you of what is missing.

■

Order of processing

When you first start processing orders, the order of the sample placed on the leftmost position on the sample area is processed first. The others follow in sequence from left to right. Once processing is in progress, the orders are processed according to sequence in which they were defined.

Repeats and reruns of routine orders are performed before routine orders.

Monitoring the analysis progress

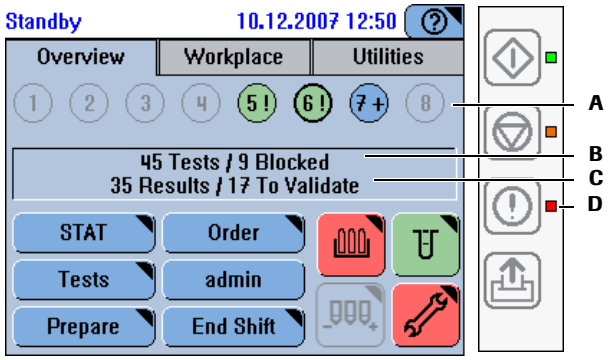
During operation, you should regularly check the following items:

- The status of the buttons on the **Overview** tab
- The Alarm Monitor LED

Checking the sample tube status

► To check the sample status

1 Press the **Overview** tab.



A Sample tube buttons
B Information on tests that are associated with defined orders
C Information on results that are associated with defined orders
D Alarm Monitor LED

Figure B-12

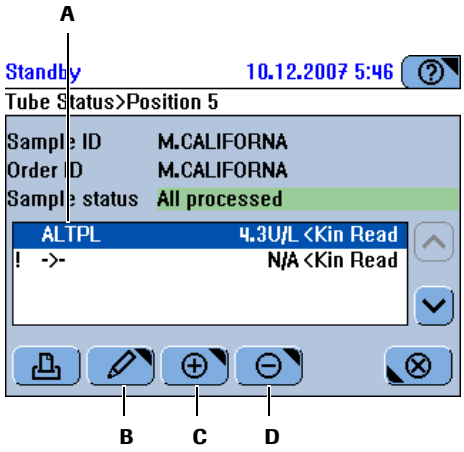
Interpreting the sample tube buttons

Icon	Meaning	Possible action
1	The number in the button denotes the position on the sample area.	n/a
◯	A sample tube button with a wide edge symbolizes a STAT order.	n/a

Icon	Meaning	Possible action
	All tests are accepted.	You can remove the sample tube.
	All tests are pipetted.	You can remove the sample tube.
	All tests are completed but not yet accepted.	Validate the results.
	All remaining tests are blocked because:	
	There is not enough sample fluid.	1. Remove the sample tube and add fluid. Do not delete the old order! 2. Scan the sample barcode or type the same sample ID as before. 3. Reinsert the sample tube. Processing continues where it stopped. (Removing a sample and then placing it again means defining a new order. The system does not remember where the sample was placed in the previous order.)
	The sample is not identified.	1. Remove the sample. 2. Scan the sample barcode or type the same sample ID as before. 3. Reinsert the sample on any position. (Removing a sample and then placing it again means defining a new order. The system does not remember where the sample was placed in the previous order.)
	There is no sample on this position.	You can place a sample tube on this position.
	Tests are ordered. Processing has not yet started.	You can still cancel ordered tests and add additional tests to the order.
	Tests are ordered. Processing has started.	You can no longer cancel ordered tests, but you can add additional tests to the order.
	The sample is identified, but no tests were ordered yet. If working in **Order Query Mode**: The order could not be obtained from the host.	This should be a temporary status. No action is required.

2 Press the sample tube button.

A screen is displayed that shows details about the status of the sample tube.



A Test name
B Press to validate the results
C Press to add tests to the order
D Press to delete the order

Figure B-13

3 Take appropriate action.

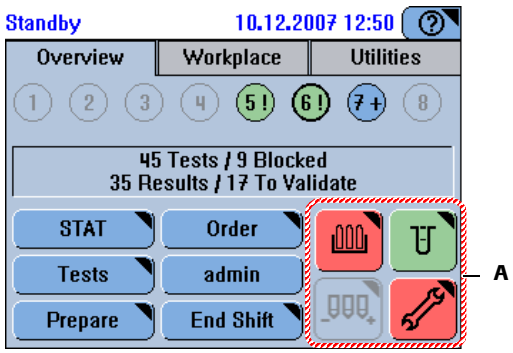
After deleting a running order, cuvettes and reagents that were not used are released again for future use.

■

Checking the instrument status buttons

► To check the instrument status

1 Press the **Overview** tab.



A Instrument status buttons

Figure B-14

Interpreting the instrument status buttons

Icon		Meaning	Possible action
		The reagents are OK.	No action is required.
		There is no disk on board.	Load a disk.
		Fewer than 10% of tests are left for a reagent set, or its expiration date has passed.	Load a new reagent set.
		A reagent set is not complete or a reagent is empty.	Complete the reagent set or replace it.
		A reagent set is blocked because it requires calibration or mixing.	Perform calibration or mixing.
		The disk could not be identified.	Remove the disk and make sure that one and only one ID tab is removed. Reinsert the disk.
		There is more than one segment available.	No action is required.
		The last available segment is in use.	Replace the used cuvette segments as soon as possible.
		There are no empty cuvettes available.	Replace the cuvette segments.
System Status	The system status button displays both the icon and the color of one of the buttons of the underlying system status screen. (The icons are first prioritized by color, first priority being red, followed by yellow and green, and then according to the sequence in which they are listed below.)		
		Analyzer (main cover)	Press the button and, on the System Status screen, check the text about the status of the main cover.
		Reagent cooler and cuvette ring temperature	Press the button and, on the System Status screen, check the text about the temperature.
		Sample area ventilation	Press the button and, on the System Status screen, check the text about the ventilation status.
		External fluid containers	Press the button and, on the System Status screen, press it again to display the screen for handling the external fluid containers.
		Maintenance	Press the button and, on the System Status screen, press it again to display the maintenance actions list.
		Printer	Press the button and, on the System Status screen, check the text about the printer status.

Checking for alarm messages

► To check for problems during processing

1 Observe the Alarm LED.

LED	Meaning	Possible action
No color (off)	There are no unconfirmed alarm messages.	No action is required.
Yellow	There is at least one unconfirmed alarm message.	User intervention is required as soon as possible. Processing can continue for the time being. Check the details of the message.
Red	There is at least one unconfirmed alarm message.	Immediate user intervention is required. Processing may not be able to continue without it. Check the details of the message.

An acoustic signal is sounded when an alarm is created. You can adjust the volume (**Utilities** > **Configuration** > **System** > **Volume**).

2 Take appropriate action.

For details on dealing with alarm messages, see *Alarm monitor* on page D-6.

■

Acoustic signal

An acoustic signal informs you of the fact that all tests are finished and the system status has changed to **Standby**.

Stopping and restarting a run

► To stop a run

1 Press the global action button.

A screen is displayed that offers several kinds of stopping, each of them representing a certain level of interrupt.

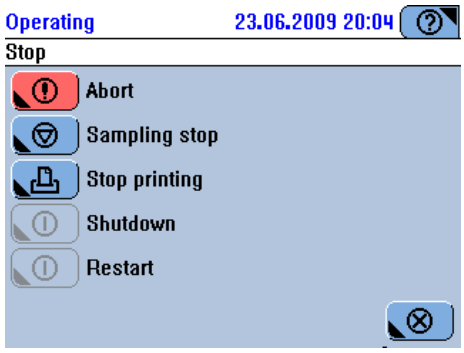


Figure B-15

Interpreting the screen

Abort	When the system is in **Operating** status: Stop immediately all processing activities. Pipettings that were not finished are considered not pipetted. Measurements that have not yielded a valid result are considered not measured.
Recover	When in **Standby** or **Stopped** status: Initialize all systems and modules that are currently not ready.
Sampling stop	Finish the current pipetting action, but do not start a new one. You can restart processing by pressing the global action button.
Stop Printing	Stop the current printing task. (It may take a few moments before printing actually stops.)
Shutdown	Shut down the **cobas c** 111 software and the operating system. This option can only be performed in **Standby** status.
Restart	Shut down the **cobas c** 111 software and automatically restart it. This option is available in **Standby** status only. It is used in cases where a configuration change requires restarting the software for it to become effective.

■

Removing sample tubes

You can remove a sample when its tube button is green .

1	All tests are accepted.
1*	All tests are pipetted.

If you remove a sample tube before the pipetting is complete, the tests that were pipetted will be performed as normal. The order remains unfinished.

You can check the resulting order details in **Workplace** > **Order** > .

See *Checking the sample tube status* on page B-44.

Validating sample results

The **cobas c** 111 instrument provides several aids for validating results:

- In the results list, results that fall outside predefined technical ranges are flagged.
- You can display detailed result information that allows you to make a considered decision.
- Non flagged results can be accepted automatically.
- You can print the results.
- You can export the results and process them on an external computer.

The following ways of dealing with results are available:

- Accept the result.
- Re-perform the identical test (**Repeat**).
- Re-perform the test using a predefined different dilution (**Rerun**).

Results must be accepted before they can be transmitted to a host or before they can be automatically printed.

Results must be accepted before they can be transmitted to a host or before they can be automatically printed.

Ratio results cannot be manually accepted. They are automatically accepted if their constituent results are accepted.

The effect of flagged results depends on the configuration (**Utilities** > **Configuration** > **Result Handling**). The following table shows how.

Configuration setting	Effect
Sample Auto Accept: On	Results that do not contain a flag are automatically accepted. Results with flags that are marked in a predefined list of flags that should be ignored are accepted as well.
Sample Auto Accept: Off	All results need to be manually accepted.
Sample Accept Flags	Flags that are marked in this list will be ignored by the system.

Table B-4 Sample flag configuration and its effect

See *Editing the acceptable flags list* on page B-162.

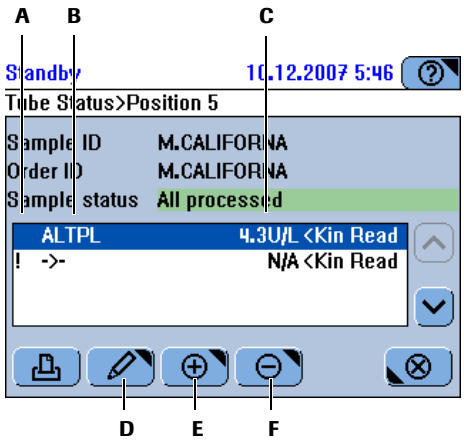
There are two main approaches to validating results:

- To validate sample results of an order whose sample is still on board, press the tube button on the **Overview** tab.
- In all other situations, choose **Workplace** > **Result Review**.

► To validate sample results of on-board samples

1 On the **Overview** tab, press the sample button.

A screen is displayed that lists the results of the order that is associated with the sample.



A Status
!: The result has not been accepted yet.
@: The result has not been transmitted yet.

B Test name.
->-: Repeated.

C Results.

D Press to validate the results.

E Press to add more tests to the order.

F Press to delete the order and its results.

Figure B-16

2 Select the result, if there is more than one test.

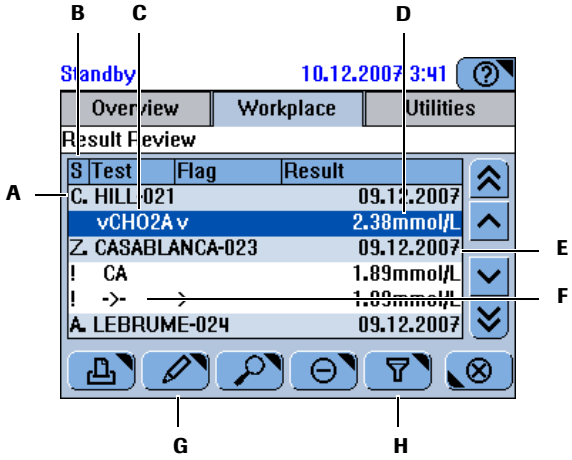
3 Continue with *Validating the results* on page B-53.

■

► To validate sample results from the results list

1 Choose **Workplace** > **Result Review**.

A screen is displayed that lists the results.



A Order number.

B Status
!: The result has not been accepted yet.
@: The result has not been transmitted yet.

C Test name.

D Results.

E Time when the order was defined.

F This test was performed again:
->-: Repeated.
-v-: Rerun with dilution.

G Press to validate the selected result.

H Press to display certain kinds of results only (filter).

Figure B-17

- To check when the result was generated press [🔍].
- For results, that were not generated on the current day, only their date of generation is displayed. You can look at the results by pressing [🔍].
- To display context information of the fluids used to arrive at this result, press [🔍], then on the detail screen press [?].

Interpreting flags

For detailed information on the flags, see *List of flags* on page D-28.

Displaying details of a result

2 Select the result.

3 Press [🔍] to display detailed information on the selected result.

4 Press [⊗] to close the screen.

The screen with the result list is displayed again.

5 Select a result.

Validating the results

The system can be set up to automatically accept results that are not flagged. In addition, it can be set up to accept results with flags that are marked in an editable list of flags that should be ignored, which is particularly suitable if the flags are assessed on the host system anyway.

See *Result handling* on page B-167.
See *Editing the acceptable flags list* on page B-162.

6 Press [✎].

A screen is displayed for selecting your reaction.

7 Do one of the following:

- Press **Repeat** to re-perform the test using the same dilution.
  See *Repeating tests* on page B-55.
- Press **Rerun** to re-perform the test using a predefined (different) dilution.
  See *Rerunning tests* on page B-56.
- Press **Accept** to accept the result.
  See *Accepting results* on page B-57.
- Press **Retransmit** to send the result to the host again. Use this function if you suspect that the result has not been stored properly on the host system, for example because of a communication problem.

■

Repeating tests

Repeat Performing a repeat means reperforming the same test with identical dilution. Typically, you perform repeats if the result is flagged and you want to confirm the result.

WARNING

Incorrect results due to insufficient fluid

Insufficient fluid may lead to inaccurate pipetting and consequently to incorrect results.

Always fill the tubes with enough fluid that at least the defined dead volume of fluid is left when pipetting is complete.

See *Tubes* on page A-54.

► To repeat a test

1 Validate the result.

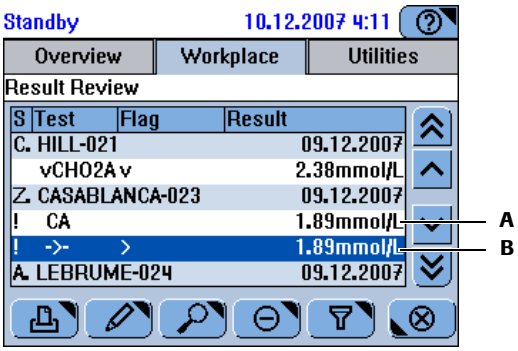
If the sample is still on board, see *To validate sample results of on-board samples* on page B-52.

If the sample is no longer on board, see *To validate sample results from the results list* on page B-53.

2 Press **Repeat**.

The system automatically creates a new order and selects the test. It then performs the test.

In the results list, the result of the repeat is shown on a separate line:



A First result **B** Repeat result (->-)

Figure B-18

■

Rerunning tests

Rerun Performing a rerun means reperforming the same test with a different predefined dilution. Typically, you perform reruns if the result is outside the test range.

WARNING

Incorrect results due to insufficient fluid

Insufficient fluid may lead to inaccurate pipetting and consequently to incorrect results.

Always fill the tubes with enough fluid that at least the defined dead volume of fluid is left when pipetting is complete.

See *Tubes* on page A-54.

► To rerun a test

1 Validate the result.

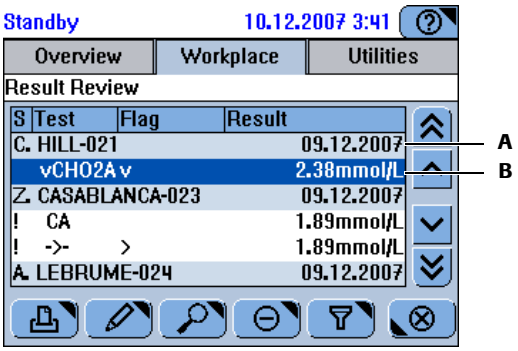
If the sample is still on board, see *To validate sample results of on-board samples* on page B-52.

If the sample is no longer on board, see *To validate sample results from the results list* on page B-53.

2 Press **Rerun**.

The system automatically creates a new order and selects the test. (The dilution factor is part of the test definition and therefore automatically selected. It cannot be changed.) It then performs the test.

In the results list, the result of the rerun is shown on a separate line:



A First measurement

B Rerun result

-v-: Rerun with dilution.

Figure B-19

■

Accepting results

Results must be accepted before they can be printed, sent to the host, or deleted.

Automatic acceptance

The system can be set up to automatically accept results that are not flagged. In addition, it can be set up to accept results with flags that are marked in an editable list of flags that should be ignored (**Utilities** > **Configuration** > **Result Handling**).

See *Result handling* on page B-167.
See *Editing the acceptable flags list* on page B-162.

► To accept a result

1 Validate the result.

If the sample is still on board, see *To validate sample results of on-board samples* on page B-52.
If the sample is no longer on board, see *To validate sample results from the results list* on page B-53.

➔ Press **Accept**.

The result list is displayed again.

Ratio results cannot be manually accepted. They are automatically accepted if all their constituent results are accepted.

■

Printing sample results

► **To print results:**

1 Do one of the following:

If	Do this
You want to print all results of an order:	Choose **Workplace** > **Orders**.
You want to print individual results:	Choose **Workplace** > **Result Review**.

2 Press .

A screen is displayed for selecting which results should be printed.

3 Press one of the buttons.

Press **List** to print the items currently displayed in the list. If a filter was applied, the list would contain only the items that fulfill the filter criterion, and the filter criterion would be part of the button name.

Press **Detail of Order** to print all results of the associated order.

For repeated or rerun orders, all results of this order are printed, including those that were accepted earlier.

■

Automatic printing You can set up the system to automatically print results as soon as all results of an order are accepted (**Configuration** > **Workflow** > **Auto Print Results**).

Choose > to terminate the printing task, if required.

Performing calibrations

For an overview on calibration concepts, see *Calibration* on page A-26.
For performing calibrations in the **Prepare** phase, see *Performing the calibrations (Prepare phase)* on page B-30.
For information on configuring calibration, see *Defining calibrator definitions and lots* on page B-150.

Tests with a due calibration are blocked.

For validating calibration results see *Validating calibration results* on page B-64.

Safety information

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Injury through reagents and other working solutions* on page B-5.
- *Infection by biohazardous materials* on page B-5.

WARNING

Skin inflammation caused by reagents

Direct contact with reagents may cause skin irritation, inflammation, or burns.

When handling reagents, be sure to wear protective equipment and observe the cautions given in the package insert.

Incorrect results due to expired calibration

Calibrations are performed to compensate for changes over time in reagents and in the measurement systems. Failing to perform calibrations when they are due may lead to incorrect results.

Make sure to perform calibrations when they are due.

Incorrect results due to wrong tube placement

Be sure to place the calibrators in the specified positions.

Incorrect results due to inappropriate tube and cup placement

Inappropriate tube and cup placement may lead to inaccurate pipetting and consequently to incorrect results.

Make sure that the primary tubes are placed centrally and perfectly vertically in the holders in the sample area and that they are inserted firmly.

Make sure that secondary tubes are placed centrally on the primary tubes and that they rest fully on them.

Short guide

The following table provides an overview on the steps that make up the calibration process.

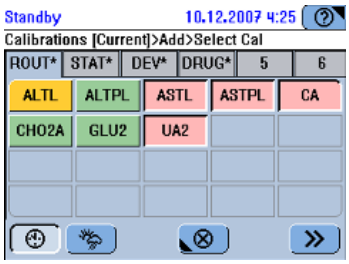
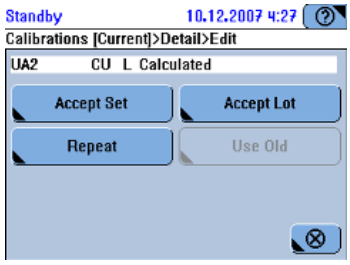
Step		User action
1	Perform the calibrations.	
	Perform all due calibrations. 	1. Choose **Workplace** > **Calibrations** > ⊕. 2. Press ⊕ to select all tests that currently need calibrating. 3. Check and, if required, print the placement list. 4. Prepare and place the calibrators according to the placement list. 5. Press ◈.
	Perform all calibrations that will be due within the forecast period.	1. Choose **Workplace** > **Calibrations** > ⊕. 2. Press ⊕ to select all tests that will require calibrating within the forecast period. 3. Check and, if required, print the placement list. 4. Prepare and place the calibrators according to the placement list. 5. Press ◈.
	Perform an individual calibration.	1. Choose **Workplace** > **Calibrations** > ⊕. 2. Select the test. 3. If there is more than one reagent set on board for this test, choose whether to calibrate the current set or to precalibrate a standby set. 4. Check and, if required, print the placement list. 5. Prepare and place the calibrators according to the placement list. 6. Press ◈.
2	Validate the results. 	1. Choose **Workplace** > **Calibrations**. 2. Select the calibration result. 3. Press 🔍 to look at result details. 4. Press ✎ to validate the calibration. 5. Remove the calibrators.

Table B-5 Steps for performing calibrations

Process of performing calibrations

The process of defining calibration orders depends on what you want to achieve:

- Calibrating all tests that need calibrating
- Calibrating all tests that will need calibrating during the forecast period
- Calibrating individual tests
  - Calibrating the current set
  - Pre-calibrating a standby set

For information on performing calibrations in the **Prepare** phase, see *Performing the calibrations (Prepare phase)* on page B-30.

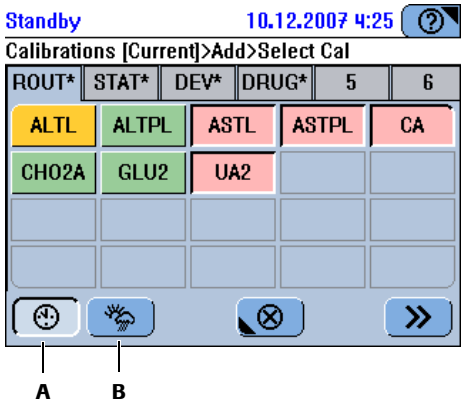
► To perform calibrations

1 Choose **Workplace** > **Calibrations**.

A screen is displayed that lists all tests and their currently valid calibration.

2 Press ⊕.

A screen is displayed that shows all active tests.



A Press to select all tests that now need calibrating.

B Press to select all tests that need calibration within the forecast period.

Figure B-20

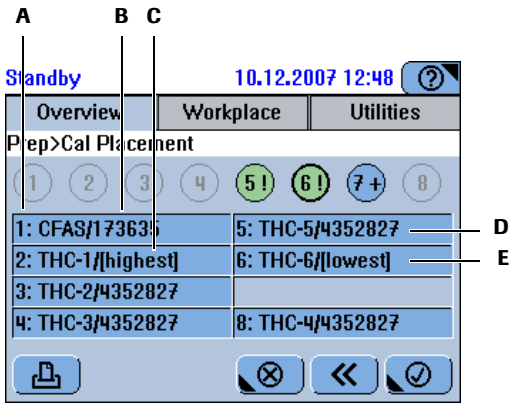
Interpreting the colors

Color	Meaning	Possible actions
	Calibration is due.	Perform the calibration.
	Calibration failed.	Check the result flag to find out why the calibration failed. Repeat the calibration if necessary.
	The calibration was successfully performed, but its result has not been accepted yet.	Validate the calibration results.
	Not relevant for calibration.	
	The calibration is OK. Its result has been accepted.	No action is currently required.
	The calibration is OK. It applies to a reagent set that is not active.	No action is currently required.

3 To select the tests, do one of the following:

If	Do this
You want to perform all due calibrations:	1. Press . All tests with due calibrations are selected. (The currently active lots and sets are used for the calibration.) 2. Press .
You want to perform all calibrations that fall due during the forecast period:	1. Press . All tests are selected whose calibration will be due within the forecast period. (The currently active lots and sets are used for the calibration.) 2. Press .
You want to calibrate the current set:	1. Select the test. 2. Press .

A screen is displayed that lists the calibrators that are required for the ordered calibrations, and it shows on which sample position to place them.



A Position on the sample area where to place the calibrator.
B Lot number
C Calibrator with highest concentration
D There are not enough empty positions, the system suggests using occupied positions.
E Calibrator with lowest concentration

Figure B-21

- The system first uses the free positions, if there are not enough free positions, occupied positions are suggested. For these you would have to replace the currently loaded tubes with calibrator tubes.
- With absorbance tests that require several calibrators, the calibrators are placed according to their concentration, starting with the highest concentration.

4 Prepare the calibrators.

5 Place the calibrators on the sample area positions indicated on the placement list.

6 Press to confirm the placement.

7 Press to start the calibration.

You can delete a running calibration order. After deleting the order, the calibration retains the **Due** status if it was due before

8 Validate the calibration results.

See *Validating calibration results* on page B-64.

9 Remove the calibrator tubes.

■

► To replace the current lot calibration

1 Choose **Workplace** > **Calibrations**.

A screen is displayed that lists all tests and their currently valid calibration.

2 Select the test whose lot calibration want to replace.

3 Press ⊖ to delete the result.

4 Press ⊘ to confirm the deletion.

5 Load the new reagent set. (See *Adding a reagent set* on page B-26.)

You can only generate a new lot calibration result when calibrating a new reagent set.

6 Choose **Workplace** > **Calibrations**.

7 Press ⊕.

8 Select the test.

9 Press ».

If a screen is displayed for selecting the calibration type, choose **Lot Master**.

10 Prepare the calibrators.

11 Place the calibrators on the sample area positions indicated on the placement list.

12 Press ⊘ to confirm the placement.

13 Press ◈ to start the calibration.

■

Deleting ordered calibrations

You can delete a calibration order while it is being processed.

► To delete an ordered calibration

1 Choose **Workplace** > **Calibrations**.

2 Select the order.

3 Press ⊖.

A confirmation dialog box is displayed.

4 Press ⊘ to confirm the deletion.

The processing activities for this order are stopped. Measurements that have not yielded a valid result are considered not measured.

■

After deleting the order, the calibration retains the **Due** status if it was due before.

Validating calibration results

For a calibration to become active, you need to accept its result.

Flagged calibration results

If flags are generated, you must determine their cause and decide whether to accept the result, continue working with the old results, or to rerun the calibration.

The effect of flagged calibration results depends on the configuration.

Configuration setting	Effect
Cal Auto Accept: On	Results that do not contain a flag are automatically accepted. Results with flags that are marked in a predefined list of flags that should be ignored are also automatically accepted.
Cal Auto Accept: Off	All results need to be manually accepted.
Cal Acceptable Flags	Flags that are marked in this list will be ignored by the system.

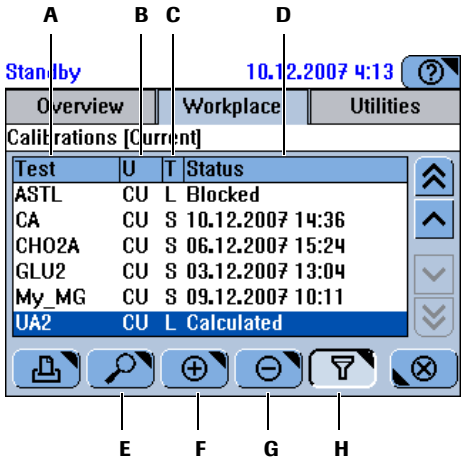
Table B-6 Calibration flag configuration and its effect

See *Result handling* on page B-167.
See *Editing the acceptable flags list* on page B-162.

► To validate the calibration results

1 Choose **Workplace** > **Calibrations**

A screen is displayed that lists all tests and their currently valid calibration.



A Test ID.
B Calibration use.
C Calibration type.
D Status indication.
E Press to validate the result.
F Press to define a new calibration order.
G Press to delete the selected calibration and its results.
H Press to display all or only the current results.

Figure B-22

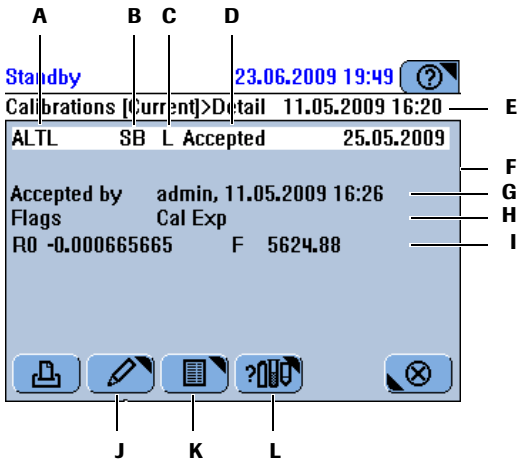
Interpreting the screen

Item	Value	Interpretation
U (Use)	CU	Current. The calibration results of this set are currently used.
	SB	Standby. The calibration results of this set are not currently used. (An identical set is currently in use or the set was removed and is not empty.)
	OB	Obsolete. The calibration results of this set are no longer used. (The set was empty and removed or it was removed more than 30 days ago).
T (Type)	L	Lot calibration (first calibration of a lot, also applies to subsequent sets of the lot).
	S	Set calibration (applies to calibrated set only).
Status		The date indicates when the results were accepted. If flags were generated for the result, the flag with the highest priority is displayed. In all other cases, the order status is displayed.

For details on calibration types, see *Calibration type* on page A-27.

2 Select the result.

3 Press [🔍] to display information on the selected calibration and its results.



A Test ID.
B Calibration use.
C Calibration type.
D Calibration status.
E Calculation date and time.
F Calibrator, lot, expiration date.
G **Accepted by**: User name. **SYS** means automatically accepted.
H Flags.
I Calibration results.
J Press to validate the results.
K Press to display result details.
L Press to display context information of the fluids used to arrive at this result.

Figure B-23

4 Press [✎].

A screen is displayed for selecting your decision.

5 Do one of the following:

- Press **Accept Set** to accept the set calibration results for the selected test.
- Press **Accept Lot** to accept the lot calibration results for the selected test.

  This button is only active if the calibration sequence **Each Lot and Interval** is defined for the application and if no flags were generated for the result.

👁 For information on lot and set calibration, see *Calibration type* on page A-27.

- Press **Repeat** to have the calibration performed again.
- Press **Use Old** to discard the new result, reset the calibration due date, and to continue using the old calibration results.

  This possibility is available if you selected an accepted result. When you press **Use Old**, a copy of the old result is made and a new entry is displayed in the calibration results list. Note that the intervals are reset as if a new calibration result were generated.

WARNING

Incorrect results when using Use Old

Calibrations are performed to compensate for changes over time in reagents and in the measurement systems. Failing to perform calibrations when they are due may lead to incorrect results.

- Roche recommend performing a QC measurement before you continue working with the old calibration results.
- In the application definitions, choose **On** for **QC After Cal**. (**Utilities** > **Applications** > **Laboratory Parameters** > **Control** > **QC After Cal**)

Accepting calibration results

Calibration results will be used by the system only when you have accepted them.

There can be only one unaccepted calibration result for a test.

If there already exists a not accepted calibration for a test and you place another calibration order for this test, the order will be blocked.

■

Performing QC

QC is performed at regular intervals to check the integrity of the whole measuring system.

Control

A control is a sample that has been measured using all tests it is associated with, in order to define the ranges and values that determine the correct functioning of the instrument. This is typically done both for the normal and the pathological analyte concentration.

For an overview on QC, see *Quality control (QC)* on page A-30.
For information on QC configuration, see *Defining control definitions and lots* on page B-149.

There are two basic ways of performing QC on the **cobas c** 111 instrument:

Default QC

Default QC is an automated process for performing QC measurements in one request. This is the ideal method if you want to perform QC on certain days or at certain times.

This process only applies to tests whose controls are defined to be performed as part of **Default QC**. Therefore, if you intend to work with **Default QC**, you need to configure the tests accordingly.

See *Defining control definitions and lots* on page B-149.

Performing **Default QC** follows a streamlined procedure whereby QC orders are automatically defined as soon as you identify a control. An order is defined for all tests for which this control is defined as the **Default QC**, provided the test is currently active on the system.

Interval QC

Interval QC is a process that is suitable both for performing a single QC measurement and for performing all QC measurements that are due. You can select all tests that require QC simply by pressing a button ( ). (This selection also reflects QC of the type **QC after Cal**.) A wizard helps you select the controls, and a placement list supports you in preparing and loading them.

Safety information

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Injury through reagents and other working solutions* on page B-5.
- *Infection by biohazardous materials* on page B-5.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page B-5.

WARNING

Incorrect results due to inappropriate tube and cup placement

Inappropriate tube and cup placement may lead to inaccurate pipetting and consequently to incorrect results.

Make sure that the primary tubes are placed centrally and perfectly vertically in the holders in the sample area and that they are inserted firmly.

Make sure that secondary tubes are placed centrally on the primary tubes and that they rest fully on them.

Short guide

The following table provides an overview of the steps that make up the QC process.

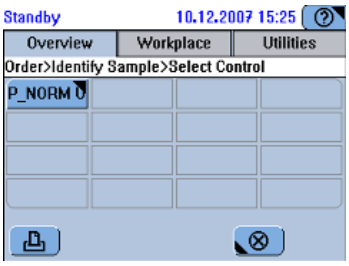
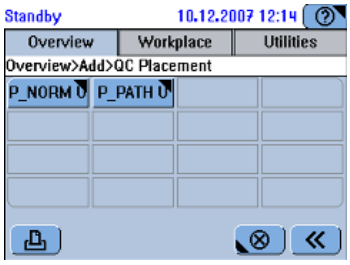
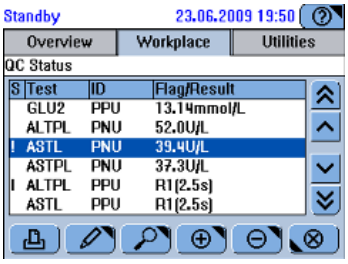
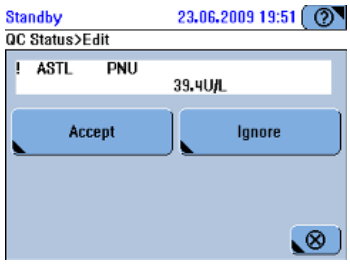
Step		User action
1	Perform QC	
	Perform **Default QC**. 	1. Choose **Overview** > **Order**. 2. Press $\$$. 3. Select a control and place the tube. Repeat until there are no controls left on the screen. 4. Press ◇.
	Perform all interval QC measurements that are due. 	1. Choose **Overview** > **Order** > $\$$ or **Workplace** > **QC Status** > ⊕. 2. Press ⊙. 3. Press ». 4. Select a control and place the tube. Repeat until there are no controls left on the screen. 5. Press ◇.
	Perform a single interval QC measurement. 	1. Choose **Workplace** > **QC Status**. 2. Press ⊕. 3. Select the test. 4. Press ». 5. Select a control and place the tube. Repeat until there are no controls left on the screen. 6. Press ◇.
2	Validate the results. 	1. Choose **Workplace** > **QC Status**. 2. Press 🔍 to look at result details. Close the details screen. 3. Press ✎ and press a button to validate the QC result. 4. Remove the controls.

Table B-7 Steps for performing QC

Performing Default QC

Performing **Default QC** follows a streamlined procedure whereby QC orders are automatically defined as soon as you identify a control. An order is defined for all tests for which this control is defined as the **Default QC**, provided the test is currently active on the system.

► To perform Default QC

1. Choose **Overview** > **Order**.
2. Press SU.

   A screen is displayed that contains a button for each of the controls that are required.
3. Prepare the controls.
4. Press a control button.

   A screen is displayed, asking you to place the selected control.
5. Place the control tube on any free position on the sample area.

   The system registers the position and automatically defines an order for each test that has this control defined as its **Default QC**.

   The screen with the control buttons is displayed again. The button for the control you just loaded is no longer active.
6. Press the next active control button.

   A screen is displayed, asking you to place the control.
7. Place the control on a free position on the sample area.
8. Select and place the remaining controls as described in steps 6 through 7.

   When all controls are placed, the screen for identifying samples is displayed.
9. Press ⊗ to close the screen.
10. Press ◈ to start processing the control orders.

■

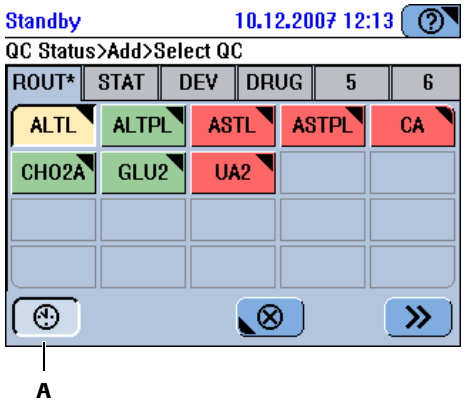
Performing interval QC measurements

► To define a QC order

1 To define a new order, do one of the following:

- Choose **Overview** > **Order** > .
- Choose **Workplace** > **QC Status** > .

A a test selection screen is displayed.



A Press to select all tests with due QC. Press again to cancel the selection.

Figure B-24

Interpreting the display

	The test is blocked for one of the following reasons: • Calibration is required. • The calibration failed. • For the reagent set, the number of available tests is 0, or a reagent bottle is missing (incomplete reagent set).
	A QC is due or its result has not yet been accepted.
	The reagent set is on board and ready for use.
	The reagent set is not on board.

2 To select the tests, do one of the following:

- Press to select all tests with due QC.

  This selection also applies to controls of the type **QC after Cal**.

- Press a test button.

3 Press .

A screen is displayed that contains a button for each of the controls that are required.

If at this stage, the required controls are already loaded on the instrument, then the QC orders are automatically created.

4 Prepare the controls.

5 Press a control button.

A screen is displayed, asking you to place the selected control.

6 Place the control tube on any free position on the sample area.

The system registers the position and automatically defines an order.

If there are more controls to place, the screen with the control buttons is displayed again. The control you just placed is no longer active.

7 Select and place the remaining controls as described in steps 5 through 6.

When all controls have been selected and placed, the **Overview** tab is displayed.

8 Press ◈ to start processing the control orders.

■

Validating QC results

Flagged QC results

If flags are generated, you must determine their cause and decide whether to accept the result or to ignore it.

The effect of flagged QC results depends on the configuration.

Configuration setting	Effect
QC Auto Accept: On	Results that do not contain a flag are automatically accepted. Results with flags that are marked in a predefined list of flags that should be ignored are also automatically accepted.
QC Auto Accept: Off	All results need to be manually accepted.
QC Acceptable Flags	Flags that are marked in this list will be ignored by the system.

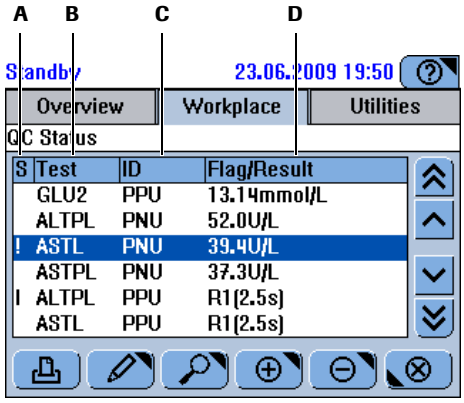
Table B-8 QC flag configuration and its effect

See *Result handling* on page B-167.
See *Editing the acceptable flags list* on page B-162.

► To validate the QC results

1 Choose **Workplace** > **QC Status**.

A screen is displayed that lists the most recent QC results for each test that is installed on the system.



A Status
!: The result has not been accepted yet.
I: The result was ignored.
@: The result has not been transmitted yet.

B Test name.

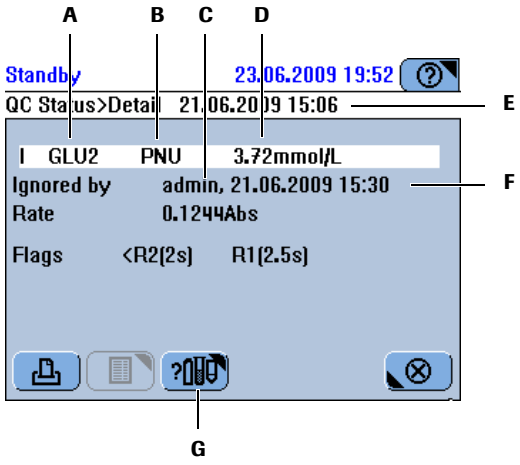
C Control ID.

D Result, if no flag was generated.
Flag with highest priority, if a flag was generated.
Order status, if the control measurement has not been performed yet.

Figure B-25

2 Select a result.

3 Press 🔍 to look at result details.



A Test name

B Control name

C Accepted by: User name. **SYS** means automatically accepted.

D Result

E Calculation date and time.

F Time when accepted.

G Press to display context information of the fluids used to perform QC for this test.

Figure B-26

4 Press ⊗ to close the screen.

If the QC result is outside the defined range, perform the QC again. If the results are still outside the range, check for other causes. If all fails, perform a calibration.

5 Press ✎.

6 Do one of the following:

- Press **Accept** to accept the QC results for the selected test.
- Press **Ignore** to exclude the result from further QC result calculations such as QC history statistics.

  When ignoring a result, the due status does not change.

  In the QC results tables, ignored QC results are marked with "**I**".

  Flags of ignored results are not inherited to dependent results.
- Press **Retransmit** to send the result again.

  (This option is active if your instrument is connected to a host system.)

■

Interpreting the QC history

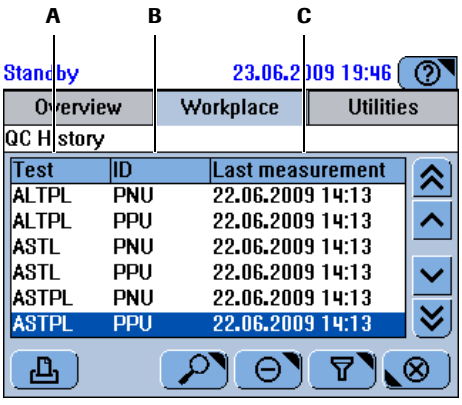
The QC history provides—on individual screens—information on the QC results of the current and the previous calendar month as well as on results that were generated before the previous month.

A graphic representation of the results provides a convenient way for comparing results over a period of time.

► To interpret the QC history

1 Choose **Workplace** > **QC History**.

A screen is displayed that contains, one QC result entry for each lot of each test.



A Test name.

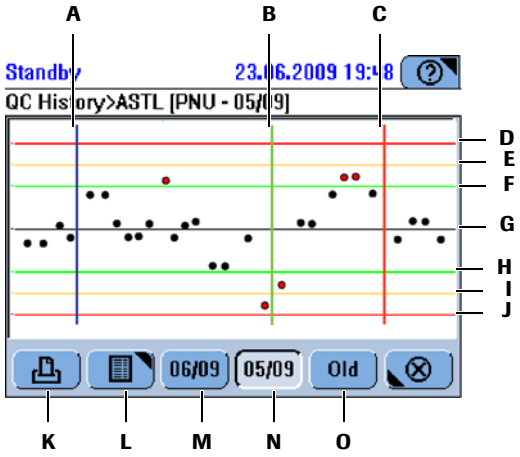
B Control ID.

C Date of most recent control. measurement. If the control does not belong to the current lot, **Previous Lot** is displayed instead of the date.

Figure B-27

2 Press .

A graphic is displayed that shows either the QC results for the current or the previous month, or those generated before the previous month.



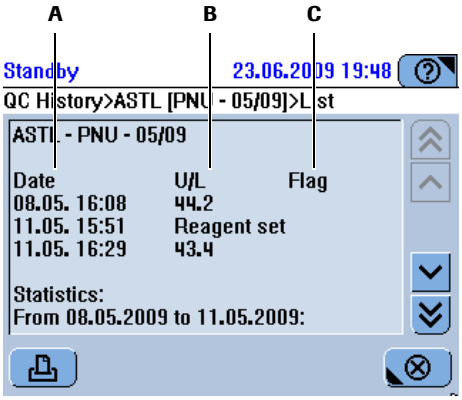
A Calibrator change
B Reagent set change
C QC target value change
D +3s
E +2.5s
F +2s
G Mean value
H -2s
I -2.5s
J -3s
K Press to print the graphic
L Press to display the results in a table
M Press to display the results of the previous month
N Press to display the results of the current month
O Press to display the results that were generated before the last month

Figure B-28

- The date format in the month selection buttons is always month/year.
- Ignored QC results are not displayed in the graph, but they are included in the **QC History** printout. Such results are marked with "**I**" at the end.
- Ignored QC results are not taken into account for QC history statistics.

3 Press [ ] to display the results in a table.

The results are sorted chronologically. An overview is followed by statistical data for all stored results and for the results of the current month. (If a QC target value change took place, only the results from this date onward are taken into account for both statistics.)



A Date of QC measurement
B Result or event
C Flag (if generated)

Figure B-29

4 Press [ ] to close the screen.

■

Performing reagent mixing

Reagents that contain Latex granules, for example D-Dimer, require periodic mixing. The mixing interval is part of the application definitions and cannot be changed by the user. The system checks every 30 minutes for reagent sets that require mixing.

For mixing during the **Prepare** phase, see *Performing reagent mixing* on page B-29.

► To perform the mixing

1 Choose **Overview** > [ ].

2 Press the button of the reagent set you want to mix.

A screen is displayed that contains details on the set.

3 Press [ ].

(This button is available if there is a mixing interval defined for this reagent set.)

Mixing starts. A screen is displayed informing you about the progress of the mixing action.

4 When mixing is finished, press [ ] to close the screen.

Closing the dialog box while mixing is in progress stops the mixing action. Mixing would have to be performed anew.

■

Finishing the shift

The typical end of shift activities are organized in a single wizard. By performing the steps as suggested by this wizard, you put the instrument in a condition that allows you to hand over operation to another operator or to switch off the instrument.

Safety information

Make sure that you have read and understood section *Safety information* on page B-5. The following safety messages in particular are relevant:

Warning messages:

- *Injury through reagents and other working solutions* on page B-5
- *Infection by biohazardous materials* on page B-5
- *Injury through reagents and other working solutions* on page B-5

WARNING

Skin inflammation caused by reagents

Direct contact with reagents may cause skin irritation, inflammation, or burns.

When handling reagents, be sure to wear protective equipment and observe the cautions given in the package insert.

Short guide

The following table provides an overview of the steps that make up the end of shift process.

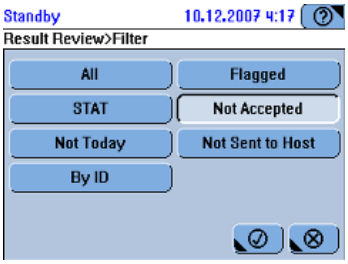
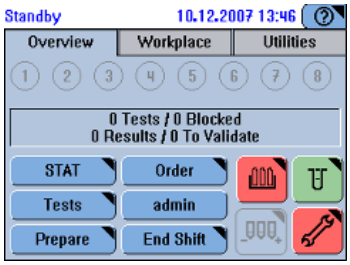
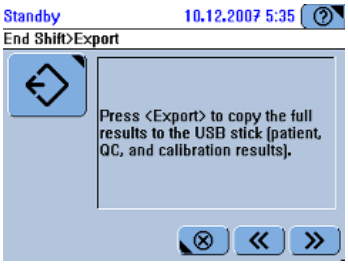
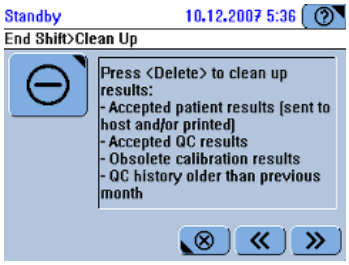
Step			User action
1	Check for unfinished tasks.		1. Check for unfinished orders. 2. Check for nonvalidated results. 3. Check for results that were not transmitted.
2	Start the **End Shift** wizard.		1. On the **Overview** tab, press the **End Shift** button.
3	Perform data backup.		1. Press . 2. Insert the USB stick. 3. Press . 4. Select the directory. 5. Press . 6. Press to proceed to the next stage in the **End Shift** wizard.
4	Export support data		1. Press . 2. Insert the USB stick, if you have removed it. 3. Press . 4. Select the directory. 5. Press . 6. Remove the USB stick. 7. Press to proceed to the next stage in the **End Shift** wizard.
5	Clean up the database.		1. Press . 2. Press to confirm the deletion. 3. Press to proceed to the next stage in the **End Shift** wizard.

Table B-9 Steps for finishing the shift

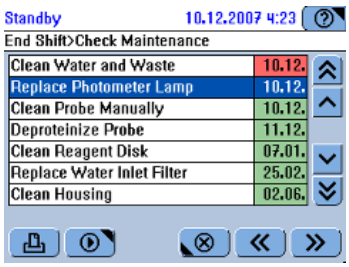
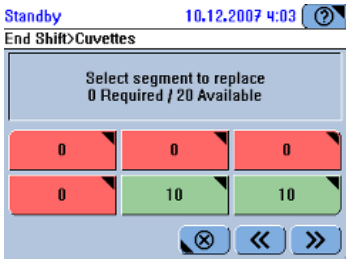
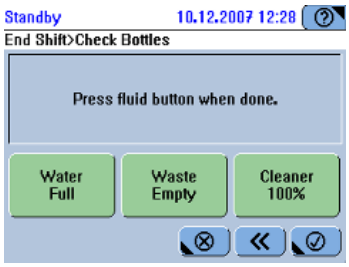
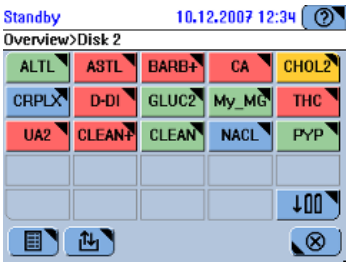
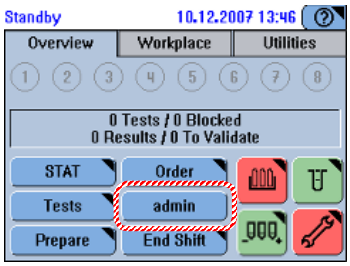
Step		User action
6	Perform maintenance actions 	1. Check which maintenance actions are due. 2. Perform the maintenance actions. Perform at least all red maintenance actions. 3. Press » to proceed to the next stage in the **End Shift** wizard.
7	Check the cuvette status. 	Replace at least all red cuvette segments. 1. Press the cuvette button. 2. Open the main cover. 3. Replace the cuvette segments. 4. Close the main cover. 5. Press » to proceed to the next stage in the **End Shift** wizard.
8	Empty the waste container. 	1. Empty the waste container. 2. Press the **Waste** button to confirm. 3. Refill the water container. 4. Press the **Water** button to confirm.
9	Remove the reagent disk. 	1. Choose **Overview** > . 2. Press 1. Open the main cover. 2. Lift the disk from the instrument. 3. Place the disk in its container. 4. Press . 5. Close the main cover. 6. Store the reagent disk in a cool place.
10	Finish your shift. 	1. Log off the system. 2. Switch off the main instrument. (If there is no other shift.)

Table B-9 Steps for finishing the shift

Checking for unfinished tasks

Checking for unfinished orders

► To check for unfinished orders

1 Choose **Workplace** > **Orders**.

2 Choose [▽] > **Not Finished**.

3 Press [✓].

A screen is displayed that contains all unfinished orders.

4 Do whatever is necessary to finish the orders.

■

Checking for not accepted sample results

Results must be accepted before they can be printed or transmitted to the host.

► To check for not accepted results

1 Choose **Workplace** > **Result Review**.

A screen is displayed that contains all sample results of the day.

2 Choose [▽] > **Not Accepted**.

3 Press [✓].

A screen is displayed that contains all sample results that have not been accepted yet.

4 Select a result.

5 Press [✎] to validate the result.

A screen is displayed for selecting your decision.

See *Accepting results* on page B-57.
See *Repeating tests* on page B-55.
See *Rerunning tests* on page B-56.

6 Press one of the buttons.

7 Select and validate the remaining results as described in Steps 4 through 6.

If you did not accept all results, deal with the not accepted ones and check for not accepted results again.

■

Checking the transmission of results

This step is only relevant if you work with a host system.

Before deleting the results, you must make sure they were properly transmitted to the host.

Results must be accepted before they can be transmitted to the host.

See also the information on *Result handling* on page B-167, in particular on the **Auto Accept** settings.

► To check for results that were not transmitted

1 Choose **Workplace** > **Result Review**.

A screen is displayed that contains all sample results of the day.

2 Choose > **Not Sent to Host**.

3 Press .

A screen is displayed that contains the sample results that have not been successfully transmitted to the host.

4 Select a result.

5 Press .

A screen for validating results is displayed.

6 Press **Retransmit**.

The list with the results that were not transmitted successfully is displayed again. The result you just retransmitted should no longer be present.

7 Select and retransmit the remaining results as described in Steps 4 through 6.

8 Choose > **Not sent to Host**.

The list should now be empty.

9 If the results were not successfully transmitted, contact the administrator of the host computer.

■

Starting the End Shift wizard

The easiest way of performing the end of shift tasks is by following the **End Shift** wizard.

► To start the End Shift wizard

1 Choose Overview > **End Shift**.

A screen is displayed for performing daily backup.

■

Performing the daily backup

The **cobas c** 111 instrument can store orders and result data for one working day. It is therefore necessary to export to an external medium all data that you need to keep.

During a database export, the full content of the database is copied to the USB stick.

The database data can be restored to the instrument if required (**Utilities** > **Import** > **Database**).

For information on restoring the database, see *Importing a database* on page B-114.

► To perform the daily backup

1 Press .

A screen is displayed, asking you to insert the USB stick.

2 Insert the USB stick.

A screen is displayed showing the directory structure of the USB stick.

3 Select the directory where you want the backup file to be copied.

4 Press to confirm the selection.

The data are copied to the stick.

Database files names have the following name format: dba_yyyymmddhhmmss.tgz.

5 Press to proceed to the next stage in the **End Shift** wizard.

A screen is displayed for deleting sample results.

■

When performing backup without using the End Shift wizard:

Choose **Utilities** > **Export** > **Database**.

Exporting the result data

When exporting results, the full result data are exported. The following results are copied to the USB stick (each of the sets is contained in a separate file):

Data set	File name
Sample results	res_yyyymmddhhmmss.csv
QC results	qcs_yyyymmddhhmmss.csv
QC history results	qch_yyyymmddhhmmss.csv
Calibration results	cal_yyyymmddhhmmss.csv
Process event log	pev_yyyymmddhhmmss.csv

File format Result data are exported as comma-separated value (csv) files. The entries are separated by semicolons (;).

For details on csv definitions, see *Exporting results* on page B-105.

These files can be processed with any spreadsheet program that can import csv files.

► To export the results

1 Press [⇦].

A screen is displayed, asking you to insert the USB stick.

2 Insert the USB stick.

A screen is displayed showing the directory structure of the USB stick.

3 Select the directory where you want the result files to be copied.

4 Press [✓] to confirm the selection.

The data are copied to the stick.

5 Press [»] to proceed to the next stage in the **End Shift** wizard.

A screen is displayed for deleting sample results.

■

When performing backup without using the End Shift wizard:

Choose **Utilities** > **Export** > **Full Results**.

Cleaning up the database

The **cobas c** 111 instrument can store orders and results data for one working day. It is therefore necessary to delete results and orders to ensure that there is enough space on the system for the next shift.

By deleting the sample results, you delete the corresponding orders as well.

► To clean up the database

1 Press ⊖.

The following results will be deleted:

- Accepted sample results.
- QC results that were accepted are deleted from the QC Status list (they remain in the QC history).
- QC results that were generated before the first day of the previous month are deleted from the QC history.
- Obsolete calibration results, provided there are more than five obsolete results for the same test.

  (Results become obsolete if the empty set was removed or if the set was removed more than 30 days ago.)

2 Press ⊘ to confirm the deletion.

The results are deleted.

3 Press » to proceed to the next stage in the **End Shift** wizard.

A screen for handling cuvettes is displayed.

■

When deleting results outside the End Shift wizard:

You can delete accepted sample results, calibrations, orders, and accepted and ignored QC results by pressing ⊖ in the respective result lists.

👁 *To delete orders* on page B-93
👁 *To delete sample results* on page B-94
👁 *To delete a calibration* on page B-95
👁 *To delete QC results from the QC Status list* on page B-97
👁 *To delete QC results from the QC History* on page B-97

Maintenance action Cleanup Database

The maintenance action **Cleanup Database** is intended for situations where the system does not work efficiently any more, it is not intended to clear up the data at the end of a shift.

Performing maintenance actions

To ensure the smooth running of the system, you should perform all due maintenance actions. Performing these actions as part of the end of shift activities ensures that at the beginning of the next shift, when there might be many tests to be performed, the system is ready for processing quickly.

► To perform maintenance actions

1 Follow the instructions given in *To perform maintenance actions* on page B-19.

2 Press [»] to proceed to the next stage in the **End Shift** wizard.

A screen is displayed that shows the status of the cuvettes.

■

When performing maintenance actions without using the End Shift wizard:
Choose **Utilities** > **Maintenance**.

Replacing cuvettes

► To replace cuvettes

1 Follow the instructions given in *To prepare the cuvettes* on page B-28.

2 Press [»] to proceed to the next stage in the **End Shift** wizard.

A screen is displayed that shows the status of the external fluid bottles.

■

When replacing cuvettes without using the End Shift wizard:
Choose **Overview** > [U].

Dealing with the external fluid bottles

Emptying the waste container

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Injury through reagents and other working solutions* on page B-5.
- *Infection by biohazardous materials* on page B-5.
- *Infection by waste solution* on page B-5.

To prevent unpleasant smells and contamination of the environment, you need to empty the waste at the end of your shift.

► To empty the waste container

1 Remove the tubing adapter from the yellow waste container and insert it in the spare container.

2 Remove the bottle from the rack and place it on a firm and even surface.

3 Place the spare container on the rack.

4 Follow the instructions given in *To check the waste container* on page B-17.

■

Roche recommend to refill the water container whenever you empty the waste container.

When emptying the waste without using the End Shift wizard:

Choose **Overview** > > .

Refilling the external water bottle

WARNING

Danger of poor measurement quality due to inadequate water quality

Inadequate water quality may lead to incorrect results. Always use purified water of the quality specified in section *Technical specifications*.

► To refill the external water container

1 Remove the tubing adapter from the white water container and place it on a clean surface.

2 Follow the instructions given in *To check the water container* on page B-16.

■

Roche recommend to empty the waste container whenever you refill the water container.

When refilling the water without using the End Shift wizard:

Choose **Overview** > > .

Removing the reagent disk

During periods when you do not perform tests, the disk should be stored in a clean refrigerated place at temperatures in the range of 2 to 8°C.

Make sure that you have read and understood section *Safety information* on page B-5. The following warning messages in particular are relevant:

- *Injury through reagents and other working solutions* on page B-5.
- *Infection by biohazardous materials* on page B-5.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page B-5.

CAUTION

Spillage through tipping reagent disk

The reagent disk container can slip off or tip over if it is not placed on an even horizontal surface.

When storing the reagent disk container, make sure to place it on a firm, even, horizontal surface that is easily accessible.

When handling the reagent disk, make sure not to tilt it.

► To remove the reagent disk

1 Choose **Overview** > > .

A screen is displayed, asking you to remove the reagent disk.

2 Open the main cover.

3 Remove the reagent disk.

4 Place the reagent disk in the reagent disk container.

5 Close the main cover.

6 Store the reagent disk container in a refrigerated place.

■

Logging off

You should log off the system before you hand it over to another operator. (Only one person can be logged on at any time.)

You can log off any time, even while the system is processing orders.

► To log off the system

1 Choose **Overview** > button with your user name.

Automatic logoff

You can configure the system to automatically log off the user after a configurable period of inactivity (**Utilities** > **Configuration** > **System** > **Screen Saver Wait** ≠ 0; **Utilities** > **Configuration** > **System** > **Auto Log-off** = **On**).

Viewing alarms while you are logged off

You can view alarms any time, even when you are logged off.

For configuring automatic logoff, see *System* on page B-168.

If there is no other shift, you can now switch off the main instrument.

■

Switching off the system

When you switch off the system, reagent cooling stops. Therefore, you need to remove the reagent disk and store it in a cool place before switching off the system.

Preconditions The system must be in **Standby** status.

► To switch off the main instrument

1 Press **O** on the toggle switch.

■

Using the barcode scanner

For information on the barcodes, see *Barcode scanner* on page A-61.

Because the barcodes on reagent bottles and sample tubes are different, you use the barcode scanner in a different way. The various procedures are described in the following sections.

WARNING

Loss of sight

The intense light of the LEDs may severely damage you eyes. Do not stare into the LEDs.

Scanning equipment using LED technology is covered by the international standard IEC 60825-1 LED Safety: Class 1.

Injury through reagents and other working solutions

Direct contact with reagents, cleaning solutions, or other working solutions may cause personal injury. When handling reagents, exercise the precautions required for handling laboratory reagents, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.

CAUTION

Malfunction due to spilled liquid

Any liquid spilled on the instrument may result in malfunction of the instrument. If liquid does spill on the instrument, wipe it up immediately and apply disinfectant.

Make sure you do not tilt the bottle or sample tube when scanning its barcode.

Reading reagent bottle barcodes

► **To use the barcode scanner for reading reagent bottle barcodes**

1. When a screen is displayed, asking you to scan, use the barcode scanner and scan the barcode.
2. Make sure not to tilt the bottle while scanning its barcode.
3. Hold the scanner at a distance of approximately 20 cm (8 in) from the barcode, pull the trigger on the scanner and point the red light just outside the barcode.
4. Move the light slowly across the barcode.
5. Wait until you hear a beep and release the trigger.

   If the reading was successful, a screen is displayed, asking you to place the bottle on the reagent disk.

■

Reading barcodes from sheets

► **To use the barcode scanner for reading barcodes from sheets**

1. When a screen is displayed, asking you to scan, use the barcode scanner and scan the barcode.
2. Place the barcode transfer sheet on a flat surface and smooth it out.
3. Hold the scanner at a distance of approximately 20 cm (8 in) from the barcode, pull the trigger on the scanner and point the red light just outside the barcode.
4. Move the light slowly across the barcode.
5. Wait until you hear a beep and release the trigger.

   If the reading was successful, a screen is displayed, asking you to place the item.

■

Reading sample tube barcodes

For safety reasons, the barcode scanner is set to only read barcodes that contain a checksum.

► **To use the barcode scanner for reading sample tube barcodes**

1. When a screen is displayed, asking you to scan, use the barcode scanner and scan the barcode.
2. Make sure not to tilt the sample tube while scanning its barcode.
3. Hold the scanner at a distance of approximately 20 cm (8 in) from the barcode, pull the trigger on the scanner and point the red light at the barcode.
4. Wait until you hear a noise and release the trigger.

   If the reading was successful, a screen for selecting tests is displayed.

■

Special operations

The tasks you do not perform every day

In this chapter, you will find information on operator tasks that are not part of the daily routine of analyzing samples.

In this chapter *Chapter* 6

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Deleting sample results B-94
Calibration B-95
Deleting calibration results B-95
Setting up your calibration schedule B-96
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Lot handling B-98
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Adjusting the touchscreen B-130
Cleaning the touchscreen B-131

Deleting sample orders

Sample orders are normally deleted as part of the daily end of shift activities. This section describes how to proceed if you need to delete sample orders outside the normal daily routine.

For deleting orders at the end of a shift, see *Cleaning up the database* on page B-84.

Preconditions for deleting

The orders should be fully processed before you delete them.

► To delete orders

1 Choose **Workplace** > **Orders**.

A screen is displayed that lists all currently defined sample orders.

2 Do one of the following:

If	Do this
You want to delete an individual order:	1. Select the order entry in the list. 2. Press ⊖. 3. Press **Selected**.
You want to delete all or a specific group of orders:	1. Press ▽. 2. Press the appropriate filter button. 3. Press ✓ to confirm the selection. 4. Press ⊖. 5. Press **List** [filter criterion].

The orders are deleted. You cannot retrieve them any more from the system.

■

- By deleting a sample order, you delete the associated results as well.
- You can delete a running order. After deleting the order, cuvettes and reagents that were not used are released again for future use

Deleting sample results

Sample results are normally deleted as part of the daily end of shift activities. This section describes how to proceed if you need to delete sample results outside the normal daily routine.

For deleting results at the end of a shift, see *Cleaning up the database* on page B-84.

Preconditions for deleting

Sample results should be accepted and printed or sent to the host before deleting.

► To delete sample results

1 Choose **Workplace** > **Result Review.**

A screen is displayed that lists all results.

2 Do one of the following:

If…	Do this…
You want to delete an individual sample result:	1. Select the result entry in the list. 2. Press ⊖. 3. Press **Selected**.
You want to delete all or a specific group of sample results:	1. Press ▽. 2. Press the appropriate filter button. 3. Press ✓ to confirm the selection. 4. Press ⊖. 5. Press **List** [filter criterion].

The results are deleted. You cannot retrieve them any more from the system.

■

By deleting all sample results of an order, you delete the corresponding order as well.

Calibration

Deleting calibration results

Obsolete calibration results are automatically deleted as part of the daily end of shift activities if there are more than five obsolete calibration results for the test. (Calibration results become obsolete when the empty set is removed or if it was removed more than 30 days ago.)

This section describes how to proceed if you need to delete results outside the normal daily routine.

For deleting calibration results at the end of a shift, see *Cleaning up the database* on page B-84.

► To delete a calibration

1. Choose **Workplace** > **Calibrations**.
2. Select the calibration entry.
3. Press ⊖.

   A confirmation screen is displayed.
4. Press ⊘.

   The order and the results are deleted. You cannot retrieve them any more from the system.

■

Setting up your calibration schedule

The **cobas c** 111 instrument provides convenient software-supported procedures for the following major calibration scenarios:

- Performing all calibrations that are currently due
- Performing all calibrations that fall due within a configurable forecast period
- Performing individual calibrations

Performing calibration as part of the Prepare wizard includes performing all calibrations that are due and that will fall due during the forecast period.

The following table lists the configurable definitions and describes their effect.

Definition item	Configuration path	Effect
Forecast Hours	**Utilities** > **Configuration** > **Calibration**	Period of time, starting with the current date, within which calibration falls due. Defining a forecast period (value other than zero) allows to concentrate calibration performance to specific days.
Cal Auto Accept	**Utilities** > **Configuration** > **Result Handling**	If on, results that are not flagged are automatically accepted. Results with flags that are marked in a predefined list of acceptable flags would also be automatically accepted.
Cal Acceptable Flags	**Utilities** > **Configuration** > **Result Handling**	List of calibration relevant flags. Flags that are marked are automatically accepted if **Cal Auto Accept** is on.

Table B-10 Calibration definitions and their effect

Deleting QC results

- QC results are displayed in the **QC Status** list as soon as they are generated. A copy of the results is also placed in the **QC History** list. This list keeps the results of the previous and the current months.
- Deleting QC results, deletes the associated orders as well.

Accepted QC results are normally deleted from the **QC Status** list as part of the daily end of shift activities, at the same time, results that were generated before the first day of the previous month are deleted from the **QC History** list.

This section describes how to proceed if you need to delete QC results outside the normal daily routine.

For deleting QC results at the end of a shift, see *Cleaning up the database* on page B-84.

► To delete QC results from the QC Status list

1 Choose **Workplace** > **QC Status**.

2 Press ⊖.

A screen for selecting results is displayed.

3 Do one of the following:

If…	Do this…
You want to delete all QC results:	1. Choose **All**. 2. Press ⊘ to confirm the deletion.
You want to delete all accepted QC results:	1. Choose **All Accepted**. 2. Press ⊘ to confirm the deletion.
You want to delete the selected result:	1. Choose **Selected**.

The results are deleted. You cannot retrieve them any more from the system.

■

► To delete QC results from the QC History

1 Choose **Workplace** > **QC History**.

2 Press ⊖.

A screen for selecting results is displayed.

3 Do one of the following:

If…	Do this…
You want to delete all results in the list: (If a filter was applied, this list would contain only the results that fulfill the filter criterion, and the filter criterion would be part of the button name.)	1. Choose **List**. 2. Press ⊘ to confirm the deletion.
You want to delete all results that were generated before the first day of the previous month:	1. Choose **Older than Previous Month**. 2. Press ⊘ to confirm the deletion.
You want to delete the results of the selected control:	1. Choose **Selected**.

The results are deleted. You cannot retrieve them any more from the system.

■

Lot handling

Both the lot data and its handling depend on what item the lot refers to:

- Calibrators (calibrator lot)
- Controls (QC lot)
- Reagents, diluents (reagent lot)

Viewing the current lot definitions

Calibrator and QC lots

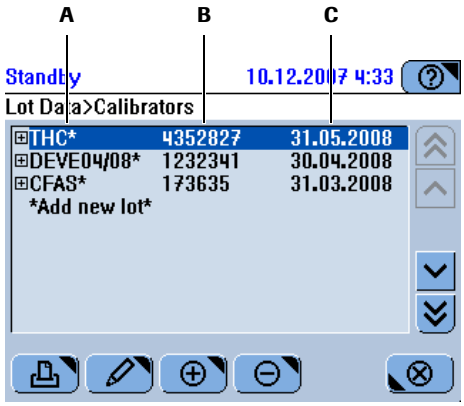
► **To view calibrator or lot data**

1 Choose **Workplace** > **Lot Data**.

2 Press either **Controls** or **Calibrators**.

A screen is displayed that lists all installed lots.

The following description shows an example of viewing a calibrator lot.



A Calibrator name.
Asterisk: The lot data were changed by the operator.
[not installed]: The associated application is not installed.

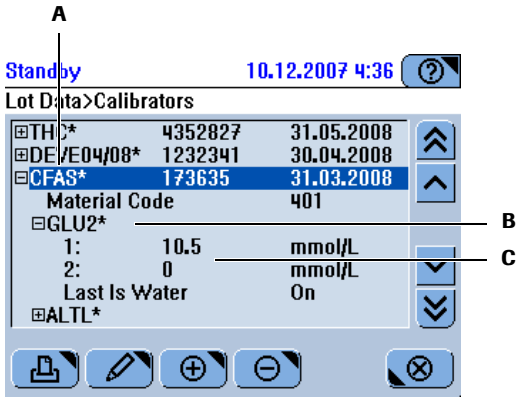
B Lot ID

C Expiration date

Figure B-30

3 Select the calibrator and expand the entry.

4 Select a test and expand the entry.



A Calibrator name
Asterisk: The lot data were changed by the operator.
[not installed]: The associated application is not installed.

B Associated test

C Lot values

Figure B-31

Calibrators that were defined or changed manually are marked with an asterisk.

■

Reagent lots

You can view the lot number in the reagent set details.

► To check the status of an individual reagent set

1 Choose **Overview** > .

2 Press a reagent set icon.

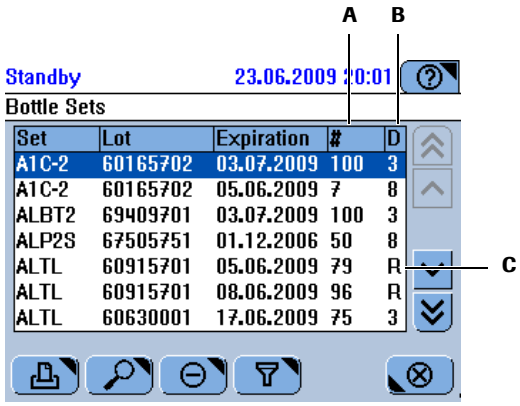
A screen is displayed that contains information on the selected reagent set, including its lot number.

■

► To gain a general overview of the currently defined reagent sets

1 Choose **Utilities** > **Inventory**.

The **Bottle sets** list is displayed. It contains all bottle sets that are defined on any of the disks used on this **cobas c** 111 instrument, including sets that were removed from the disk, as long as they were not empty or their expiration date has not passed yet.



A Number of tests left

B ID of reagent disk on which the set is defined

C **R** indicates that the set was removed from the disk.

Figure B-32

2 Select a set and press [🔍].

A dialog box is displayed that contains detailed set information.

3 Press [?].

A dialog box is displayed that contains set, calibration, and QC information.

4 Press [⊗] to close the dialog boxes until the **Utilities** tab is displayed.

■

Viewing the lot details of fluids that were used

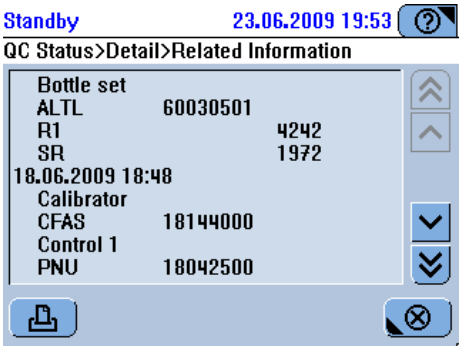
For sample, calibration, and QC results, you can check to which lot the used fluids belong (reagents, calibrators, controls).

► To check context information of a result

1 Do one of the following:

If	Do this
You want to check the context information of a sample result:	1. Choose **Workplace** > **Result Overview**. 2. Select a result. 3. Choose > .
You want to check the context information of a QC result:	1. Choose **Workplace** > **QC Status**. 2. Select a result. 3. Choose > .
You want to check the context information of a calibration result:	1. Choose **Workplace** > **Calibrations**. 2. Select a result. 3. Choose > .

A screen is displayed that lists the lot IDs for the used reagent set, calibrators, and controls. (The following figure shows an example of sample-result lot-data.)



2 Scroll to display the information, if required.

3 Press to close the screen.

■

Adding a new lot

Lot data are usually contained in the barcode of the item, and you define them by scanning the barcode. With the exception of reagent and diluent lots—they can be defined by scanning their barcodes only—all lots can also be defined manually.

Defining lots manually requires utmost diligence

During lot definition you need to type data that are directly relevant to result generation.

You would for example define the lot data manually if you cannot read the barcode for some reason, or in the case where you work with lab-specific controls or third-party controls that do not include barcode transfer sheets for lot data.

Preparation tasks Make sure that the controls and calibrators are assigned to the application.

See *Preparing applications* on page B-140.

► To define a control lot

1. Choose **Workplace** > **Lot Data**.
2. Press **Controls**.

   A screen is displayed that lists all installed control lots.
3. Press ⊕.

   A screen is displayed, asking you to scan the barcode transfer sheet or to type the data manually.
4. Define the lot values.

   Do one of the following:

If…	**Do this**…
The lot data are available from a barcode	1. Scan the barcode. The screen is displayed again that lists all installed control lots. The new lot is selected.
You want to type the data manually	1. Press ⌨. 2. Type the name and press ». 3. Type the material code and press ». You find this code in **Utilities** > **Applications** > select a test > ✎ > **Control**. 4. Type the Lot ID and press ». 5. Type the expiration date. Use the date format as indicated on the screen. 6. Press ✓ to confirm the definitions. If a lot with the same ID already exists on the system, a screen is displayed, asking you whether you want to replace the existing lot. Press ✓ to confirm the definitions. 7. Press ***Add new test***. 8. Press ⊕. A screen is displayed that contains all tests that use this control and that have not yet been assigned to this lot. 9. Select a test and press ». 10. Type the value for the mean concentration and press ». 11. Type the value for the standard deviation. 12. Press ✓ to confirm the definitions. The screen for handling control lot data is displayed again. 13. Perform steps 7 through 12 for all tests you want to use.

■

► To define a calibrator lot

1 Choose **Workplace** > **Lot Data**.

2 Press **Calibrators**.

A screen is displayed that lists all installed calibrator lots.

3 Press ⊕.

A screen is displayed, asking you to scan the barcode or to type the data manually.

4 Define the lot values. Do one of the following:

If…	Do this…
The lot data are available from a barcode	1. Scan the barcode. The screen is displayed again that lists all installed calibrator lots. The new lot is selected.
You want to type the data manually	1. Press ⌨. 2. Type the name (up to 10 alphanumeric characters) and press ». 3. Type the material code and press ». Refer to the package insert. 4. Type the lot ID (up to nine alphanumeric characters) and press ». 5. Type the expiration date and press ». Use the date format as indicated on the screen. 6. Type the number of calibrators (cups) you need to place on the instrument. Use the information given on the package insert. (Exclude calibrators that use system water from this number. See step 14.) 7. Press ✓ to confirm the definitions. 8. Press ***Add new test***. 9. Press ⊕. A screen is displayed that shows all tests that have this calibrator defined for them and that are not yet assigned to this lot. 10. Press one of the test buttons. 11. Press ». 12. Define the first calibration value (target value). 13. Define the next calibration value. You can define up to six calibration values, and you must define them in descending order. 14. Select the value for **Last is Water**. Press **On** if you want to calibrate with system water as zero calibrator. (In this case, no cup needs to be placed on the system. (See step 7). Press **Off** if you want to use a special zero calibrator for the calibration. (The special zero calibrator needs to be placed on the sample area.) 15. Press ✓ to confirm the definitions.

Calibration values (target values) in method sheets may be defined in increasing order of concentration. Always define the values in *decreasing* order on the **cobas c** 111 instrument.

■

Exporting data

➔ **Utilities** > **Export**

Exporting the database

The database is normally exported as part of the daily backup during the end of shift activities.

See *Performing the daily backup* on page B-82.

During a database export, the full content of the database is copied to the USB stick.

The database data can be restored to the instrument if required.

See *Importing a database* on page B-114.

► To export the database

1. Choose **Utilities** > **Export** > **Database**.

   A screen is displayed, asking you to insert the USB stick.
2. Insert the USB stick.
3. Press ⊘.
4. Select the directory.
5. Press ⊘ to confirm the selection.

   The data are copied to the USB stick.

   Database files names have the following name format:
   dba_yyyymmddhhmmss.tgz.

■

Exporting results

When exporting results, the full result data are copied into an archive on the USB stick.

The archive has the name format csv_yyyymmddhhmmss.tgz, and it contains the following files:

Data set	File name
Sample results	res_yyyymmddhhmmss.csv
QC results	qcs_yyyymmddhhmmss.csv
QC history results	qch_yyyymmddhhmmss.csv
Calibration results	cal_yyyymmddhhmmss.csv
Process event log	pev_yyyymmddhhmmss.csv

File format

Result data are exported as line-oriented comma-separated value (csv) files.

The following definitions apply:

- Character set: ISO1LATIN1 - ANSI - ISO8859-1 - ISO Latin 1, Western
- Separator: Semicolon (;)
- Element qualifier: Quote (“) (ASCII-Code 34 (0x22)
- Empty element: Two quotes (“”) (ASCII-Code 34 (0x22)
- Line terminator: Standard Win Style (CRLF) ASCII-Code 13+10 (0x0D + 0x0A)

These files can be processed with any spreadsheet program that can import csv files.

► To export the support data

1 Choose **Utilities** > **Export** > **Full Results**.

A screen is displayed, asking you to insert the USB stick.

2 Insert the USB stick.

3 Press ⊘.

4 Select the directory.

A screen is displayed for selecting a directory.

Press <*.csv> to archive files only.

Press <*.*> to display all files and directories.

5 Press ⊘ to confirm the selection.

The data are copied to the USB stick. The screen for exporting data is displayed again.

■

Interpreting result data

The following tables list, for the sample, calibration, and QC result files, the column headings of the spreadsheet and provide information on the kind of information the columns contain.

res_yyyymmddhhmmss.csv

Column Title	Description
Instr	Instrument ID (always 30 for **cobas c** 111)
Msg	Message Type:
	7 Result for sample, control, or calibration
Index	166 ID of the data set used
App	Application code
Date	Date when the result was calculated
Time	Time when the result was calculated
SW-Version	Software version installed on the instrument
Serial	Serial number of the instrument
Test	Short name of the application
User	User name (**SYS** if **Auto Accept** is on)
Sample	Sample ID
Order-Time	Time when the order was started
Result	Results of the measurement
Unit	Defined display unit
Flags	Flag name
Rates	Rate value calculated in Abs. (**Last Calculation Point** - **First Calculation Point**)
Raw1 - Raw40	Absorbance value of cycle 1 through 40 in Abs. (one cycle = 18 s)
isSTAT	Generated as part of a STAT order

Table 33 Explanations on test results

cal_yyyymmddhhmmss.csv

Column Title	Description	
Instr	Instrument ID (always 30 for **cobas c** 111)	
Msg	Message Type:	
	7	Result for sample, control, or calibration
Index	151	Calibration data
	152	Std-1 value
	153	Std-2 value
	154	Std-3 value
	155	Std-4 value
	156	Std-5 value
	157	Std-6 value
App	Application code	
Date	Date when the result was generated	
Time	Time when the result was calculated	
SW-Version	Software version installed on the instrument	
Serial	Serial number of the instrument	
Cal/Std	Calibrator ID (C.f.a.s. = 401) and standard number	
User	User name (**SYS** if **Auto Accept** is on)	
Lot	Lot number	
LS/Value	Calibration type/Target value of corresponding calibrator	
	L	Lot calibration
	S	Set calibration
Unit	Defined display unit	
Flags	Flag name	
R0/Rate	Offset and factor of the calibration curve	
Kc/Raw01	Kc parameter value or absorbance value of cycle 1 in Abs.	
A/Raw02	A parameter value or absorbance value of cycle 2 in Abs.	
B/Raw03	B parameter value or absorbance value of cycle 3 in Abs.	
C/Raw04	C parameter value or absorbance value of cycle 4 in Abs.	
Raw05 - Raw40	Absorbance value of cycle 5 through 40 in Abs. (one cycle = 18 s)	
Test	Short name of the application	

Table 34 Explanations on calibration results

If the calibration results were accepted using **Use Old**, "**???**" is displayed as the **Date** and **Time** values, and the corresponding values for **Raw1** - **Raw40** are missing.

qcs_yyyymmddhhmmss.csv

Column Title	Description
Instr	Instrument ID (always 30 for **cobas c** 111)
Msg	Message Type:
	7 Result for sample, control, or calibration
Index	161 Data values
App	Application code
Date	Date when the result was generated
Time	Time when the result was calculated
SW-Version	Software version installed on the instrument
Serial	Serial number of the instrument
Ctrl	Control ID
User	User name (**SYS** if **Auto Accept** is on)
Lot	Lot ID
Mean	Mean value
Result	Result value
Unit	Defined display unit
Flags	Flag name
Rate	Rate value calculated in Abs. (**First Calculation Point** - **Last Calculation Point**)
Raw1 - **Raw40**	Absorbance value of cycle 1 through 40 in Abs. (one cycle = 18 s)
Test	Short name of the application
Ignored	"I" if the QC result was ignored

Table 35 Explanations on QC results

qch_yyyymmddhhmmss.csv

Column Title	Description
Instr	Instrument ID (always 30 for **cobas c** 111)
Msg	Message Type:
	8 QC history result
Index	151 Data values
App	Application code
Date	Date when the result was calculated
Time	Time when the result was calculated
SW-Version	Software version installed on the instrument
Serial	Serial number of the instrument
Ctrl	Control ID
User	User name (**SYS** if **Auto Accept** is on)
Lot	Lot ID
Mean	Mean value
Result	Result value
Unit	Defined display unit
Flags	Flag name
SD	Standard deviation
Test	Short name of the application
Ignored	"I" if the QC result was ignored

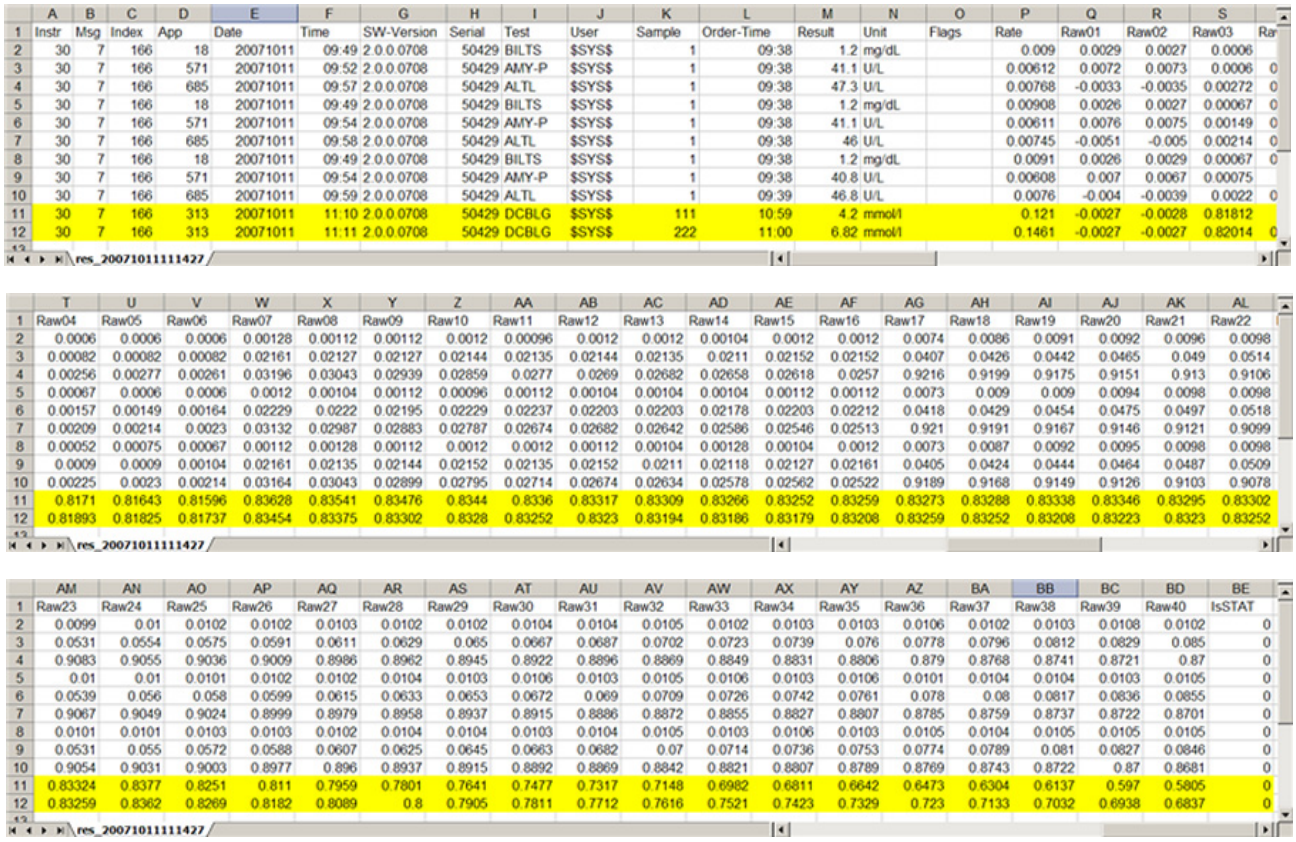
Table 36 Explanations on QC history results

pev_yyyymmddhhmmss.csv

Column Title	Description	
Instr	Instrument ID (always 30 for **cobas c** 111)	
Msg	Message Type:	
	9	Process event
Index	191	Reagent usage changed
	192	Calibrator assigned valued changed
	193	QC assigned valued changed
	199	Other process event
App	Application code	
Date	Date when the event took place	
Time	Time when the event took place	
SW-Version	Software version installed on the instrument	
Serial	Serial number of the instrument	
Event	Description of the event	
User	User name (**SYS "system user"** = **???** if nobody is logged in)	
Test	Short name of the application	

Table 37 Explanations on process events

The following figure is an example of a test result file that was opened in a spreadsheet tool. Rows 11 and 12 represent the raw data of a development channel application with the short name DCBLG.



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	Instr	Msg	Index	App	Date	Time	SW-Version	Serial	Test	User	Sample	Order-Time	Result	Unit	Flags	Rate	Raw01	Raw02	Raw03
2	30	7	166	18	20071011	09:49	2.0.0.0708	50429	BILTS	SYS	1	09:38	1.2	mg/dL		0.009	0.0029	0.0027	0.0006
3	30	7	166	571	20071011	09:52	2.0.0.0708	50429	AMY-P	SYS	1	09:38	41.1	U/L		0.00612	0.0072	0.0073	0.0006
4	30	7	166	685	20071011	09:57	2.0.0.0708	50429	ALTL	SYS	1	09:38	47.3	U/L		0.00768	-0.0033	-0.0035	0.00272
5	30	7	166	18	20071011	09:49	2.0.0.0708	50429	BILTS	SYS	1	09:38	1.2	mg/dL		0.00908	0.0026	0.0027	0.00067
6	30	7	166	571	20071011	09:54	2.0.0.0708	50429	AMY-P	SYS	1	09:38	41.1	U/L		0.00611	0.0076	0.0075	0.00149
7	30	7	166	685	20071011	09:58	2.0.0.0708	50429	ALTL	SYS	1	09:38	46	U/L		0.00745	-0.0051	-0.005	0.00214
8	30	7	166	18	20071011	09:49	2.0.0.0708	50429	BILTS	SYS	1	09:38	1.2	mg/dL		0.0091	0.0026	0.0029	0.00067
9	30	7	166	571	20071011	09:54	2.0.0.0708	50429	AMY-P	SYS	1	09:38	40.8	U/L		0.00608	0.007	0.0067	0.00075
10	30	7	166	685	20071011	09:59	2.0.0.0708	50429	ALTL	SYS	1	09:39	46.8	U/L		0.0076	-0.004	-0.0039	0.0022
11	30	7	166	313	20071011	11:10	2.0.0.0708	50429	DCBLG	SYS	111	10:59	4.2	mmol/l		0.121	-0.0027	-0.0028	0.81812
12	30	7	166	313	20071011	11:11	2.0.0.0708	50429	DCBLG	SYS	222	11:00	6.82	mmol/l		0.1461	-0.0027	-0.0027	0.82014

	T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL
1	Raw04	Raw05	Raw06	Raw07	Raw08	Raw09	Raw10	Raw11	Raw12	Raw13	Raw14	Raw15	Raw16	Raw17	Raw18	Raw19	Raw20	Raw21	Raw22
2	0.0006	0.0006	0.0006	0.00128	0.00112	0.00112	0.0012	0.00096	0.0012	0.0012	0.00104	0.0012	0.0012	0.0074	0.0086	0.0091	0.0092	0.0096	0.0098
3	0.00082	0.00082	0.00082	0.02161	0.02127	0.02127	0.02144	0.02135	0.02144	0.02135	0.0211	0.02152	0.02152	0.0407	0.0426	0.0442	0.0465	0.049	0.0514
4	0.00256	0.00277	0.00261	0.03196	0.03043	0.02939	0.02859	0.0277	0.0269	0.02682	0.02658	0.02618	0.0257	0.9216	0.9199	0.9175	0.9151	0.913	0.9106
5	0.00067	0.0006	0.0006	0.0012	0.00104	0.00112	0.00096	0.00112	0.00104	0.00104	0.00104	0.00112	0.00112	0.0073	0.009	0.009	0.0094	0.0098	0.0098
6	0.00157	0.00149	0.00164	0.02229	0.0222	0.02195	0.02229	0.02237	0.02203	0.02203	0.02178	0.02203	0.02212	0.0418	0.0429	0.0454	0.0475	0.0497	0.0518
7	0.00209	0.00214	0.0023	0.03132	0.02987	0.02883	0.02787	0.02674	0.02682	0.02642	0.02586	0.02546	0.02513	0.921	0.9191	0.9167	0.9146	0.9121	0.9099
8	0.00052	0.00075	0.00067	0.00112	0.00128	0.00112	0.0012	0.0012	0.00112	0.00104	0.00128	0.00104	0.0012	0.0073	0.0087	0.0092	0.0095	0.0098	0.0098
9	0.0009	0.0009	0.00104	0.02161	0.02135	0.02144	0.02152	0.02135	0.02152	0.0211	0.02118	0.02127	0.02161	0.0405	0.0424	0.0444	0.0464	0.0487	0.0509
10	0.00225	0.0023	0.00214	0.03164	0.03043	0.02899	0.02795	0.02714	0.02674	0.02634	0.02578	0.02562	0.02522	0.9189	0.9168	0.9149	0.9126	0.9103	0.9078
11	0.8171	0.81643	0.81596	0.83628	0.83541	0.83476	0.8344	0.8336	0.83317	0.83309	0.83266	0.83252	0.83259	0.83273	0.83288	0.83338	0.83346	0.83295	0.83302
12	0.81893	0.81825	0.81737	0.83454	0.83375	0.83302	0.8328	0.83252	0.8323	0.83194	0.83186	0.83179	0.83208	0.83259	0.83252	0.83208	0.83223	0.8323	0.83252

	AM	AN	AO	AP	AQ	AR	AS	AT	AU	AV	AW	AX	AY	AZ	BA	BB	BC	BD	BE
1	Raw23	Raw24	Raw25	Raw26	Raw27	Raw28	Raw29	Raw30	Raw31	Raw32	Raw33	Raw34	Raw35	Raw36	Raw37	Raw38	Raw39	Raw40	IsSTAT
2	0.0099	0.01	0.0102	0.0102	0.0103	0.0102	0.0102	0.0104	0.0104	0.0105	0.0102	0.0103	0.0103	0.0106	0.0102	0.0103	0.0108	0.0102	0
3	0.0531	0.0554	0.0575	0.0591	0.0611	0.0629	0.065	0.0667	0.0687	0.0702	0.0723	0.0739	0.076	0.0778	0.0796	0.0812	0.0829	0.085	0
4	0.9083	0.9055	0.9036	0.9009	0.8986	0.8962	0.8945	0.8922	0.8896	0.8869	0.8849	0.8831	0.8806	0.879	0.8768	0.8741	0.8721	0.87	0
5	0.01	0.01	0.0101	0.0102	0.0102	0.0104	0.0103	0.0106	0.0103	0.0105	0.0106	0.0103	0.0106	0.0101	0.0104	0.0104	0.0103	0.0105	0
6	0.0539	0.056	0.058	0.0599	0.0615	0.0633	0.0653	0.0672	0.069	0.0709	0.0726	0.0742	0.0761	0.078	0.08	0.0817	0.0836	0.0855	0
7	0.9067	0.9049	0.9024	0.8999	0.8979	0.8958	0.8937	0.8915	0.8886	0.8872	0.8855	0.8827	0.8807	0.8785	0.8759	0.8737	0.8722	0.8701	0
8	0.0101	0.0101	0.0103	0.0103	0.0102	0.0104	0.0104	0.0103	0.0104	0.0105	0.0103	0.0106	0.0103	0.0105	0.0104	0.0105	0.0105	0.0105	0
9	0.0531	0.055	0.0572	0.0588	0.0607	0.0625	0.0645	0.0663	0.0682	0.07	0.0714	0.0736	0.0753	0.0774	0.0789	0.081	0.0827	0.0846	0
10	0.9054	0.9031	0.9003	0.8977	0.896	0.8937	0.8915	0.8892	0.8869	0.8842	0.8821	0.8807	0.8789	0.8769	0.8743	0.8722	0.87	0.8681	0
11	0.83324	0.8377	0.8251	0.811	0.7959	0.7801	0.7641	0.7477	0.7317	0.7148	0.6982	0.6811	0.6642	0.6473	0.6304	0.6137	0.597	0.5805	0
12	0.83259	0.8362	0.8269	0.8182	0.8089	0.8	0.7905	0.7811	0.7712	0.7616	0.7521	0.7423	0.7329	0.723	0.7133	0.7032	0.6938	0.6837	0

Figure 3 Example of spreadsheet representation of a test result raw data file

Exporting log files

During troubleshooting, you may be asked to export the log files and to send them to by the service representative for examination.

The log-files contain the alarm messages and system logs.

► To export the log files

1 Choose **Utilities** > **Export** > **Log Files**.

A screen is displayed, asking you to insert the USB stick.

2 Insert the USB stick.

3 Press ⊘ to confirm the insertion.

A screen is displayed for selecting a directory.

Press ***.tgz** to display **cobas c**111system files only.

Press ***.*** to display all files and directories.

4 Select the directory.

5 Press ⊘ to confirm the definitions.

The data are copied to the USB stick. The screen for exporting data is displayed again.

■

Importing data

➔ **Utilities** > **Import**

You can import the following kinds of data:

- Application data (application definitions)
- Software (software updates)
- Database (as exported using **Utilities** > **Export** > **Database**)
- Certificates (digital records that ensure the authenticity of reagent barcodes)
- Extra wash cycle and mixing rule definitions

Importing applications

Importing an application consists of two steps:

1. Importing the data to the instrument by reading a barcode or a data file. This step stores the data on the instrument.
2. Installing the application. This step activates the application on the instrument and so makes it available for use.

► To import application data

1 Do one of the following:

- Choose **Utilities** > **Applications** > **Laboratory Parameters**, then continue with step 2.
- Choose **Utilities** > **Import** > **Application**, then continue with step 4.

2 Press ⊕.

3 Press **Import Application**.

A screen is displayed, asking you to scan the barcode or to import the data from the USB stick.

4 Do one of the following:

If…	**Do this**…
You intend to scan the barcode:	1. Scan the barcode from the barcode sheet.
You intend to import from the USB stick:	1. Press ⇔. 2. Insert the USB stick. 3. Press ⊘. 4. Select the directory that contains the application file. You recognize the application packages by their file extension .tsb. 5. Press ⊘ to confirm the selection.

The system checks whether there is already an application on the system with identical application code and short name.

The following table lists the basic situations.

If…	This happens…
Both, the application code and the short name exist:	The laboratory parameters, for example the short name, are retained from the existing application. The application definitions are replaced on the system by the new ones.
The application code exists, and the short name does not exist for any application on the system:	The laboratory parameters of the new application are used, for example the short name. The application definitions are replaced on the system by the new ones.
The short name exists, but the application code does not:	A screen is displayed for changing the short name to a unique short name. If you do not change the short name, the application is not imported.

For detailed information on possible conflicts when importing applications, see the section on installing and configuring development channel applications in the **cobas c** 111 Development Channel Operator's Manual.

If you want to replace both the laboratory parameters and the application definitions, you first need to uninstall and delete the existing application and then to import the new application.

If the application you are importing is a development channel application, note the following possible exceptional situations:

Situation	Explanation and possible actions
No crypto module is installed.	A message is displayed, informing the operator of this fact. The system does not import the application.
The maximum number of development channel applications is already installed.	A message is displayed, informing the operator of this fact. 1. Uninstall and then delete a development channel application. 2. Start the import process again.

The applications list (**Utilities** > **Applications** > **Laboratory Parameters**) is displayed. The application name is displayed in square brackets, for example [GLU2], to indicate that the application is not installed yet.

To make the application available for performing tests, you now need to install it.

■

► To install an application

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Select an application whose name is in square brackets.

3 Press ⊕.

4 Choose **Install Application**.

The system checks whether there is already an application installed on the system with identical application code or short name.

In the applications list, the application name is displayed without brackets and in the profile details the short name is displayed.

The profiles that use this application are included in the test selection screen, provided that all applications of the profiles are installed.

5 Prepare the application.

See *Preparing applications* on page B-140.

■

Importing software

This function is usually used for installing software updates.

► To import system software

1 Choose **Utilities** > **Import** > **Software**.

A screen is displayed, asking you whether you want forced download of controller software, that is whether you want to overwrite the current controller firmware irrespective of its current status.

2 Do one of the following:

- Press ⊘ to overwrite the controller firmware .
- Press ⊗ to perform standard import.

A screen is displayed, asking you to insert the USB stick.

3 Insert the USB stick.

4 Press ⊘.

5 Select the software package.

You recognize the software packages by their file extension .tar.

6 Press ⊘ to confirm the selection.

The software is installed on the system. A message will inform you when the installation is complete.

The system will automatically reboot.

When the import is complete, the **Overview** tab is displayed, and the system is in Standby status.

■

Importing a database

Compatibility

- If the version of the imported database is older than the one on the target system, the imported database will be converted to the version on the system.
- If the version of the imported database is more recent than the one on the target system, the database cannot be imported.

Typical situations

Importing a database is mainly done in the following situations:

- You want to restore your existing system to a previous status, for example from a backup version of the database that was generated on the same system.
- You want to install a known system setup on another system (cloning).

The following table illustrates the different effects in the two situations.

Data item	Identical source and target system	Different source and target systems
Installed applications	Overwrite	Write, overwrite if present
System configuration	Overwrite	Write, overwrite if present
Bottle set inventory	Overwrite	Write, overwrite if present
Bottle sets	Mark as removed	Mark as removed
Lot information for calibrators and controls	Overwrite	Write, overwrite if present
Sample orders and results	Overwrite	Delete if present
QC orders and results	Overwrite	Delete if present
QC history results	Overwrite	Delete if present
Calibration orders and results	Overwrite	Delete if present
Abs. Air/Water Calibration	Delete	Delete if present
Administrator password	Reset to default value	Reset to default value
Electrode definitions	Delete	Delete if present
ISE fluid bottle definitions	Delete	Delete if present

Table B-11 Effects on existing data when importing a database

► To import the database

1. Remove all bottles of all bottle sets of all disks defined on the target system, using the appropriate software features.

   👁 See *Preparing the reagents* on page B-22.

2. Choose **Utilities** > **Import** > **Database**.

   A confirmation screen is displayed, informing you about the major effects of the import.

   👁 For details see Table B-11 on page B-114.

3. Press ⊘.

   A screen is displayed, asking you to insert the USB stick.

4. Insert the USB stick.

5. Press ⊘.

6 Select the database file.

Typically, the file format looks like this: dba_yyyymmddhhmmss.tgz.

Press ***.tgz** to display **cobas c** 111system files only.

Press *.* to display all files and directories.

7 Press ✓ to confirm the selection.

When the data are imported, a message is displayed, asking you to restart the system.

8 Choose ⏻ > **Restart** to restart the system.

■

After the database installation

- Load all bottle sets that are defined, using the appropriate software features.
- Perform **Abs. Air/Water Calibration** maintenance action.

Importing certificates

Certificates are digital records that ensure the authenticity of reagent barcodes. On each **cobas c** 111 instrument there must be a certificate installed.

► To import certificates

1 Choose **Utilities** > **Import** > **Certificate**.

A screen is displayed, that lists the currently installed certificates.

2 Press ⇨.

A screen is displayed, asking you to insert the USB stick.

3 Insert the USB stick.

4 Press ✓.

5 Select the certificate.

You recognize a certificate by its file extension .prm.

6 Press ✓ to confirm the selection.

The certificates are installed on the system.

The screen is displayed again, that lists the currently installed certificates.

■

Importing automatic mixing and extra wash cycle definitions

Mixing and extra wash cycle information is contained in a separate barcode on a barcode transfer sheet.

► **To import mixing and extra wash cycle information**

1 Choose **Utilities** > **Import** > **EWC/Mixing**.

A screen is displayed, asking you to scan the barcode.

2 Scan the barcode.

The data are installed on the system. A message will inform you when the installation is complete. The screen for importing data is displayed again.

👁 For information on defining extra wash cycles see *Defining extra wash cycles* on page B-170.

■

Preparing a new disk

WARNING

Injury through reagents and other working solutions

Direct contact with reagents, cleaning solutions, or other working solutions may cause personal injury.

When handling reagents, exercise the precautions required for handling laboratory reagents, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Personal injury or damage to the analyzer due to contact with instrument mechanism

Contact with moving parts of the instrument may cause personal injuries, stop the instrument from processing, and cause damage to instrument parts.

- Do not touch moving parts during instrument operation.
- Keep all covers closed, operate them as instructed on the screen.

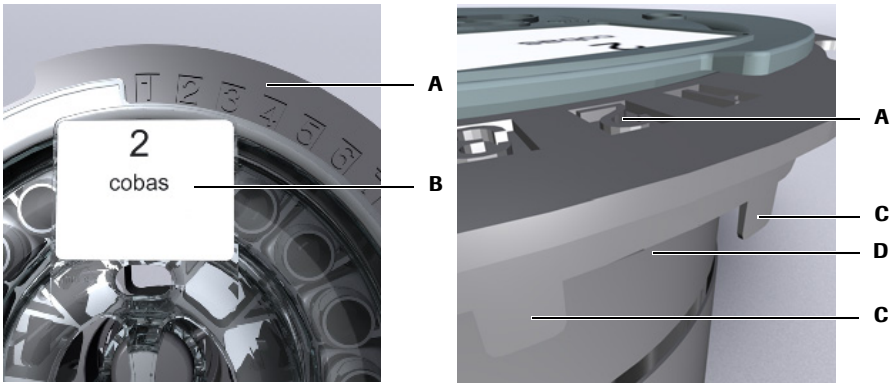
NOTICE

Damage to the reagent disk

The reagent disk is designed to handle reagents while it is loaded on the instrument. The cover is equipped with a locking mechanism.

Remove or insert bottles only when the reagent disk is loaded on the instrument and always use the software functions to perform these tasks.

You can use up to eight different reagent disks on one **cobas c** 111 instrument. Each reagent disk is equipped with numbered tabs. For automatic disk identification by the instrument, one—and only one—of these tabs is removed. The number of this removed tab is the disk ID. When you label the disk, make sure that the number on the label corresponds to that of the removed tab.



A Reagent disk IDs. There are eight possible IDs.

B Disk label. The number must correspond to the reagent disk ID.

C Identification tabs

D The tab has been removed for automatic disk recognition

Figure B-38 Reagent disk ID

► To prepare a new reagent disk

Defining the disk ID

1. Be sure to select an ID that is not used by any other reagent disk you intend to use on this **cobas c** 111 instrument.

   You can choose a number between one and eight.

2. Print the number on a label and stick the label on the disk (A).

3. Using pliers, break off the ID tab (C, D) with the same number as the one printed on the label.

Loading the disk

4. On the system, choose Overview > .

   A disk overview screen is displayed.

5. Press .

   A screen is displayed, asking you to insert the disk.

6. Open the main cover.

7. Place the reagent disk in the reagent cooler.

   Make sure the reagent port faces the front and align the cut-outs with their counterparts on the reagent cooler.

   The system automatically detects that a disk was inserted.

   A screen is displayed, asking you to close the main cover.

8 Close the main cover.

At this stage, the system identifies the disk.

A screen is displayed that shows the status of the reagent sets.

Loading reagent sets

9 Press [↓00].

A screen is displayed, asking you to scan the bottle barcode.

10 Scan the barcode on the bottle.

11 Remove the cap from the bottle and place it in the reagent bay.

12 Press [✓] to confirm the insertion.

If you confirm without placing the bottle, the system assumes that the bottle is placed.

If you press [⊗] after placing the bottle, the position is deemed empty.

When the first reagent bottle of a set is loaded, the reagent set is defined. From this moment on, the reagents are handled as part of the set. You no longer handle them as individual reagents.

13 Do one of the following:

If	Do this
There is another bottle belonging to the set:	A screen is displayed, asking you to scan the bottle. 1. Scan the bottle 2. Insert the bottle. 3. Press [✓] to confirm the insertion.
All bottles of the set are inserted:	1. Close the main cover. On the screen with the reagent set buttons, the button for the new set is now present.

14 Press [⊗].

15 On the disk overview screen, press [↓00] to load the next reagent. Proceed as described in steps 10 through 15.

■

Assigning tests to test tabs

The system provides two order modes: Easy and Full. When working in Easy mode, the test selection screen consists of one panel, if working in Full mode, the screen contains up to six panels, each is identified by a tab.

To make a test available for selection from the test selection screen, you need to assign it to a test tab. This is done in two steps:

1. Naming the tabs (if required).
2. Assigning the tests to the tabs.

You need Lab Manager or Administrator rights for assigning tests to tabs.

Assignment when importing applications

When you import applications, the tests are assigned to the tabs as follows:

- If you work in Easy mode, the tests are added to the Easy panel. (If the panel is full, they will not be displayed.)
- If you work in Full mode, the tests are added to the Easy panel (if there is space) and to the first Full mode tab. If there is not enough space on the first Full mode tab, the test is added to the next tab that has space available.

► To name a test tab

1 Choose **Utilities** > **Configuration** > **Workflow**.

2 Expand the **Workflow** entry, scroll down, and select **Test Tab 1...6 Name**.

3 Press [ ].

A screen for typing text is displayed.

For details on typing text see *Typing text* on page A-76.

4 Type up to four characters.

This is the name of the tab on the screen for assigning tests.

5 Press [ ].

The tab name is now available on the screen for assigning tests. See below.

■

► To assign a test to a tab

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Select the test you want to assign to a tab.

3 Press [ ].

4 Select **General** and expand the entry.

5 Select **Test Tabs**.

6 Press [ ].

A screen is displayed that provides a button for each of the possible tabs.

The **Easy** button is always available. It is the standard panel for working in **Easy** order mode. (You cannot rename it.)

7 Select the buttons for all the tabs where the test should be displayed.

8 Press ✓.

The tests are now available on the corresponding tabs on the test selection screen.

■

► **To remove a test from a tab**

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Select the test you want to remove.

3 Press ✎.

4 Select **General** and expand the entry.

5 Select **Test Tabs**.

6 Press ✎.

7 Cancel the selection of the button of the tab to which the test is assigned to.

8 Press ✓.

The test is no longer available from the corresponding tab on the test selection screen.

■

To move a test from one tab to another, delete it from the original tab and assign it to the new tab.

Deleting bottle sets from the Inventory list

The **Inventory** list serves to gain an overview on the status of all bottle sets that are defined on any of the reagent disks used on the **cobas c** 111 instrument.

You can delete bottle sets from the list; this would be appropriate if you removed a set from the disk and did not intend to use it again.

- Before you can delete a bottle set from the **Inventory** list you need to remove it from the disk.
- Bottle sets that have been removed from the disk and whose expiration date had passed more than 30 days ago are automatically deleted from the **Inventory** list, provided there is still a valid set for the same fluid on board. If this were not the case, the set that was loaded last would remain in the inventory.

► **To delete a bottle set from the Inventory list**

Removing the bottle set

1 Remove the bottle set from the disk.

👁 *Removing a reagent set* on page B-25.

If the bottle set that you want to delete is not on the currently installed disk, you need to change the disk first.

👁 *Removing the reagent disk* on page B-87, *Preparing the reagent disk* on page B-21.

Deleting the bottle set

2 Choose **Utilities** > **Inventory**.

The **Bottle sets** list is displayed. It contains all bottle sets that are defined on any of the disks used on this **cobas c** 111 instrument, including sets that were removed from the disk, as long as they were not empty or their expiration date has not passed yet.

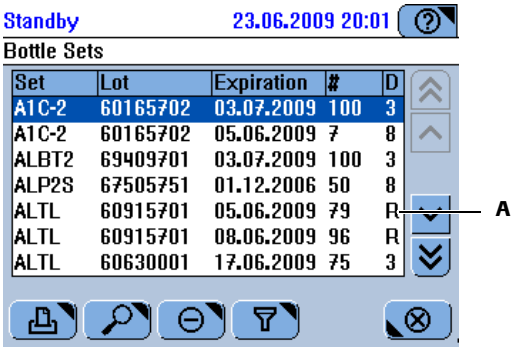


Figure B-39

In the **D** column, removed bottle sets are marked with **R** (**A**).

3 Select the bottle set you want to delete.

4 Press ⊖

A confirmation dialog box is displayed. If the set cannot be deleted a message will inform you.

5 Press ✓ to confirm the deletion.

■

It is not possible to place a bottle set on a reagent disk again, once it was deleted from the **Bottle sets** list.

Refilling printer paper

You can refill the printer paper any time, provided printing is not in progress.

► To check the printer status

1 On the **Overview** tab, press the System status button.

The printer button is red if the printer is out of paper.

2 Scroll to display the **Printer** entry and read the text.

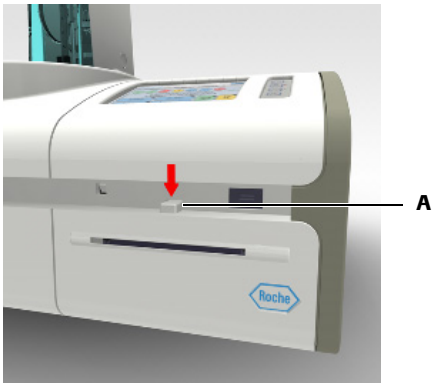
■

► To replace the printer paper

1 Make sure the printer is not currently printing.

2 Open the printer panel.

Be sure to press down the release button (A) firmly *before* you pull the panel. The panel should open without resistance.



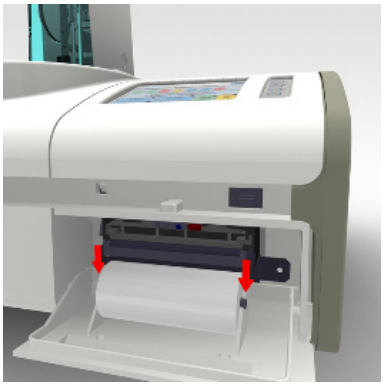
3 Lift the empty printer paper roll from its holder.

4 Remove the pin from the roll.

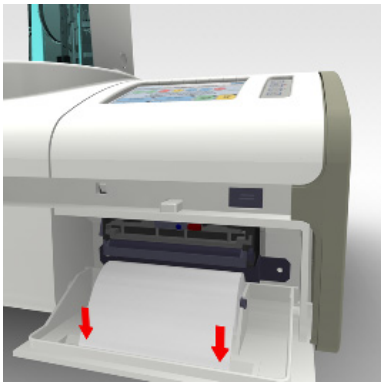
5 Insert the pin in the new roll.

6 Place the new roll on the holder.

Make sure the paper unrolls at the top and towards you.



7 Insert the paper in the slot in the printer panel and pull some through.



8 Close the printer panel.

The system feeds some paper.

If the system ran out of paper during printing, it will resume printing.

9 On the **Overview** tab, press the System status button.

The printer button should now be green, and the status description should be **OK**.

■

Removing condensation water from the reagent cooler

► **To remove water from the reagent cooler**

1 Make sure the system is in **Standby** status.

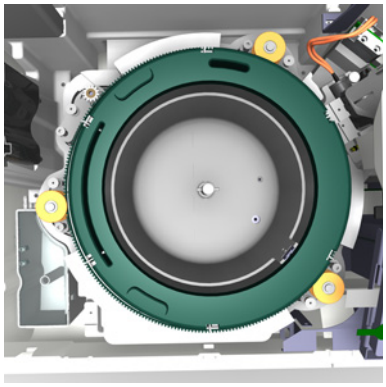
2 Choose **Overview** > > .

3 Open the main cover.

4 Remove the reagent disk.

Be sure not to tilt it and place it on an even surface.

5 Wipe the inside of the reagent cooler with a cloth or paper to remove the water.



6 Insert the reagent disk.

7 Close the cover.

■

Replacing the probe

If the probe is bent, broken, or corroded, you need to replace it.

Tools and materials required

- Probe and tubing set
- Tube with ISE Deproteinizer
- Tube with Activator
- Glass beaker

WARNING

Injury through working solutions

Direct contact with cleaning solutions or other working solutions may cause personal injury. When handling such solutions, exercise the precautions required for handling them, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics cleaning solutions.

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

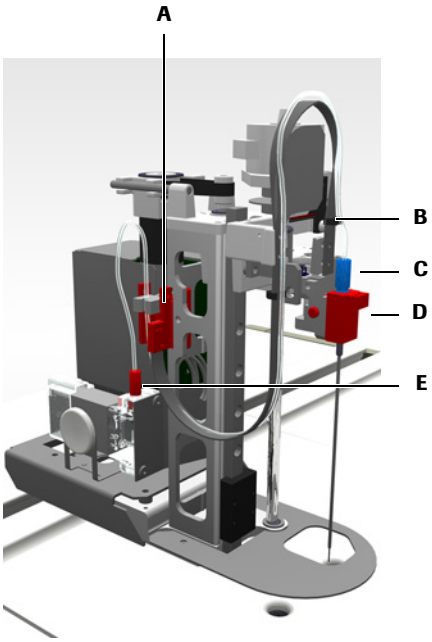
- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

► To remove the probe

1. Make sure the system is in **Standby** status.
2. Switch off the system.
3. Remove the transfer head cover.

   Press the release buttons on both sides and lift.
4. Release the tube leading to the probe from all tubing clips.

5 Remove the sensor tubing adapter (A).



A Sensor tubing adapter
B Example of tubing clip
C Tube fixation screw on holder
D Probe holder
E Tube fixation screw on distribution block

Figure B-40

6 Remove the probe holder (D) from the carriage.

Press the release button on the side of the probe holder carriage and lift the probe holder with the probe.

7 Unscrew the probe from its holder and remove it from it.

8 Place the probe in the beaker and the probe holder on a clean surface.

9 Unscrew the tubing from the distribution block (E).

10 Lift the tubing and wait until all fluid has run into the beaker.

11 Dispose of the probe assembly. Treat it as biohazardous waste.

■

► To install the new probe

1 Carefully insert the probe in the probe holder and fasten the screw that fixes the tubing to the holder (C).

2 Reinstall the probe holder with the probe.

Press the release button on the side of the probe holder carriage while you insert the probe holder. Release the button when the holder is inserted.

Push the holder firmly down until the release button latches on.

3 Reinstall the sensor tubing adapter.

Push down until the clips engage.

4 Screw the tubing to the distributor block.

5 Fix the tube to all tubing clips. Start near the probe holder.

6 Install the transfer head cover.

Push down until the release buttons latch on.

7 Switch on the system.

The system performs internal checks and routines.

The startup phase may take a few minutes.

When the instrument is ready for use, the **Overview** tab is displayed, and its status is **Standby**.

8 Log on the system.

9 Perform the **Deproteinize Probe** maintenance action.

See *Deproteinize the probe* on page C-10.

■

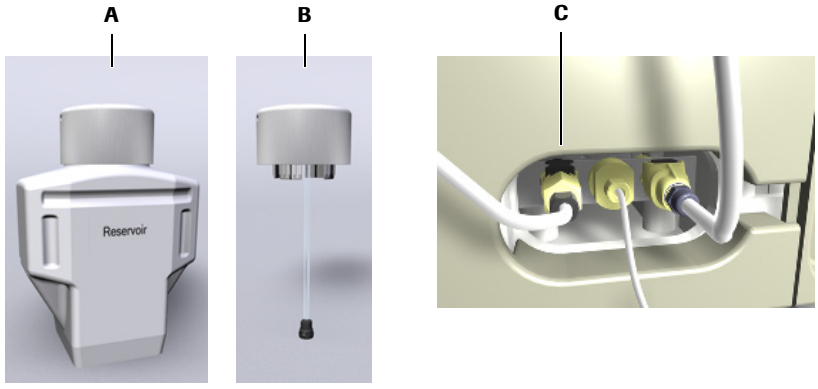
Connecting and disconnecting the external fluid containers

Before switching on the system, make sure that all external fluid containers are placed on the rack and properly connected.

► To connect the water container

1 Place the white full water container on the tray. (Always use purified water of the quality specified in section *Technical specifications*.)

2 Connect the water tubing to the connector on the instrument by pushing the plug firmly in the socket.



A Water container
B Tubing adapter
C Water connector

Figure B-41

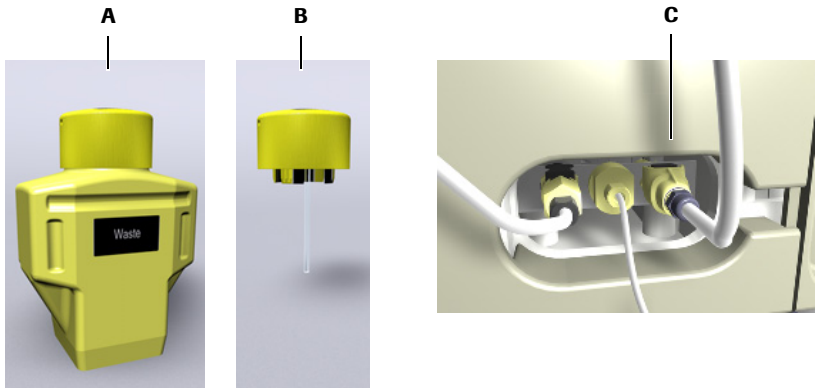
3 Insert the tubing adapter in the container and push it down firmly.

■

► To connect the waste container

1 Place the empty yellow waste container on the tray.

2 Connect the waste tubing by pushing the plug firmly in the socket.



A Waste container
B Tubing adapter
C Waste connector

Figure B-42

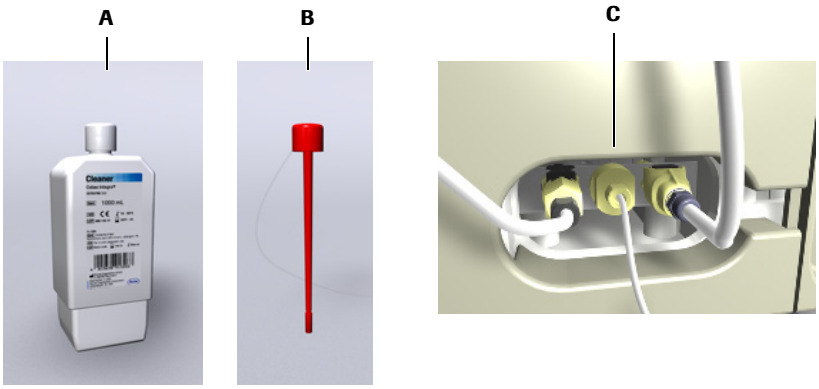
3 Insert the tubing adapter in the container and push it down firmly.

■

► To connect the cleaner bottle

1 Place the bottle on the tray.

2 Screw the cleaner tubing to the connector on the instrument. Do not fasten the screw too tight.



A Cleaner bottle
B Tubing adapter
C Cleaner connector

Figure B-43

3 Insert the tubing adapter in the container and push it down firmly.

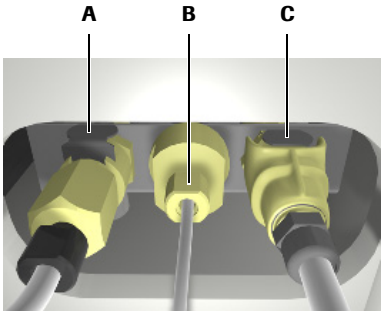
■

► To disconnect a tube from the instrument

1 Remove the right side panel.

2 Do one of the following:

If	Do this
You want to disconnect the water tubing:	Press down the release clamp (A) on the connecting socket and pull the connector away from the socket.
You want to disconnect the diluent tubing:	Turn the connecting screw (B) counter-clockwise until the connector is released.
You want to disconnect the waste tubing:	Press down the release clamp (C) on the connector and pull the connector away from the socket.



A Release clamp on water connecting socket **C** Waste connector release clamp.
B Diluent connector screw

Figure B-44

■

Adjusting the touchscreen

With a touchscreen, it is important that the point where you press the screen corresponds exactly with its hardware equivalent. If this were not the case, pressing a screen item such as a button might not lead to the expected result.

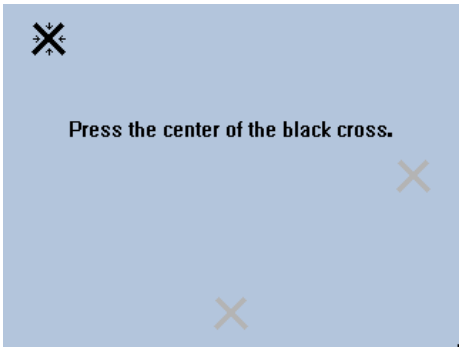
► To adjust the touchscreen

1. Press the global button.

   A screen is displayed that offers several kinds of stopping.

2. Press the global button again.

   A screen for adjusting the screen is displayed.



3. Press exactly in the center of the black cross.

   The cross turns green and the next cross turns black.

4. Press exactly in the center of the black cross.

   The cross turns green and the next cross turns black.

5. Press exactly in the center of the black cross.

   All crosses are green.

6. Press anywhere in the screen and observe where exactly a small red square (pixel) is displayed.

   The red square should be exactly where you pressed.

7. Do one of the following:

If	Do this
The red square is exactly where you pressed:	1. Press .
The red square is some distance from where you pressed:	1. Press . 2. Repeat the whole procedure, make sure that you press exactly in the center of the crosses.

■

Cleaning the touchscreen

Because the touchscreen gets easily soiled you should clean it regularly.

Tools and materials required

- ☐ 70% ethyl alcohol
- ☐ Tissues
- ☐ Protective gloves

► To clean the touchscreen

1 Pour or spray some alcoholic solution on a tissue.

2 Wipe the screen.

Exert as little pressure as possible.

3 Wipe the screen with a clean tissue.

■

Configuration

Integrating the system in your environment

In this chapter, you will find information on how to define the way you work with the **cobas c** 111 instrument.

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Introduction

The process for viewing and changing configuration and application values is the same. The following procedures use the example of a calibration value.

Viewing values

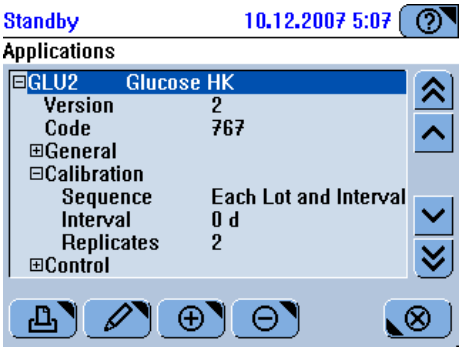
► To view values

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Expand the list.

- Select a list item marked with ⊞.
- Press ⊘.
- Select a sublist item marked with ⊞.
- Press ⊘.
- Use the scrollbar, if required, to display the items you are interested in.

The definition items and their current values are displayed.



■

Changing values

If the change of a value results in one or several other values needing to be changed, a wizard is started when you change the first value. You recognize a wizard by the presence of the » and « buttons.

► To change a value

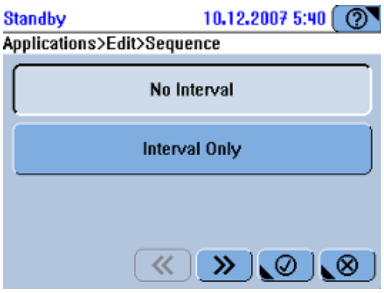
1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

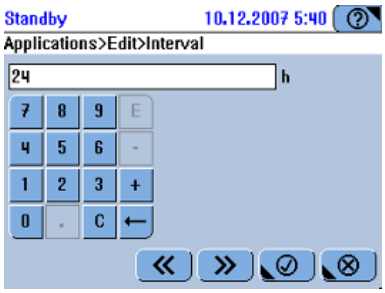
2 Expand the list to display the items and their values.

3 Select an item that shows a value.

4 Press .

A screen is displayed where you either can type a new value or select one by pressing its corresponding button.





5 Type the new value or press a value button.

6 Do one of the following:

If	Do this
You are in a wizard and want to change a further value:	1. Press . A screen is displayed for changing the value. 2. Type the new value or press a value button. 3. Continue with step 6. 4. When is no longer active, press to confirm the changes.
This was the only value you want to change:	1. Press to confirm the changes.

■

Applications

Installing applications

To make available a new application on a **cobas c**111 instrument, you need to perform the following steps:

1. Import the data to the instrument by reading its barcode or by reading them from a USB stick. This step saves the data on the instrument.

   It is possible to import a new version of an application with identical application code, but you cannot install it.

   To import application data on page B-137.
2. Install the application. This step activates the application on the instrument and so makes it available for use.

   Installing applications on page B-137.
3. Prepare the application. This step associates the application with lot data and auxiliary fluids such as calibrators and controls.

   To prepare an application on page B-140.

► To import application data

1 Do one of the following:

- Choose **Utilities** > **Applications** > **Laboratory Parameters**, then continue with step 2.
- Choose **Utilities** > **Import** > **Application**, then continue with step 4.

2 Press ⊕.

3 Press **Import Application**.

A screen is displayed, asking you to scan the barcode or to import the data from the USB stick.

4 Do one of the following:

If…	**Do this**…
You intend to scan the barcode:	1. Scan the barcode from the barcode sheet.
You intend to import from the USB stick:	1. Press ◇. 2. Insert the USB stick. 3. Press ⊘. 4. Select the directory that contains the application file. You recognize the application packages by their file extension .tsb. 5. Press ⊘ to confirm the selection.

The system checks whether there is already an application on the system with identical application code and short name.

The following table lists the basic situations.

If…	This happens…
Both, the application code and the short name exist:	The laboratory parameters, for example the short name, are retained from the existing application. The application definitions are replaced on the system by the new ones.
The application code exists, and the short name does not exist for any application on the system:	The laboratory parameters of the new application are used, for example the short name. The application definitions are replaced on the system by the new ones.
The short name exists, but the application code does not:	A screen is displayed for changing the short name to a unique short name. If you do not change the short name, the application is not imported.

For detailed information on possible conflicts when importing applications, see the section on installing and configuring development channel applications in the **cobas c** 111 Development Channel Operator's Manual.

If you want to replace both the laboratory parameters and the application definitions, you first need to uninstall and delete the existing application and then to import the new application.

If the application you are importing is a development channel application, note the following possible exceptional situations:

Situation	Explanation and possible actions
No crypto module is installed.	A message is displayed, informing the operator of this fact. The system does not import the application.
The maximum number of development channel applications is already installed.	A message is displayed, informing the operator of this fact. 1. Uninstall and then delete a development channel application. 2. Start the import process again.

The applications list (**Utilities** > **Applications** > **Laboratory Parameters**) is displayed. The application name is displayed in square brackets, for example [GLU2], to indicate that the application is not installed yet.

To make the application available for performing tests, you now need to install it.

■

► To install an application

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Select an application whose name is in square brackets.

3 Press ⊕.

4 Choose **Install Application**.

The system checks whether there is already an application installed on the system with identical application code or short name.

In the applications list, the application name is displayed without brackets and in the profile details the short name is displayed.

The profiles that use this application are included in the test selection screen, provided that all applications of the profiles are installed.

5 Prepare the applications.

See *Preparing applications* on page B-140.

■

Activating and deactivating applications

When an application is installed on the system, it is automatically activated.

Installing applications on page B-137.

You can deactivate an application to temporarily make unavailable the test on the test panel. All associated fluids and data remain unchanged. You can activate the application later again and continue using the test.

► To activate or deactivate an application

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Expand the application entry.

3 Expand the **General** entry.

4 Select **Active**.

5 Press .

6 Choose **On** if you want to use the application.

Choose **Off** if you do not want to use the application.

7 Press .

■

Preparing applications

Perform following steps for each new application. (Use the wizards to make the definitions.)

For the general procedure of making changes to definitions, see *To change a value* on page B-135.

► To prepare an application

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Expand the application entry.

Code

The Roche application code identifies the application. It is used for host communication. If you work with a different code for a particular application, you need to map the Roche application code to your own code.

See *Mapping the host codes* on page B-162.

This code is also used on the **cobas c** 111 Printer Tool. (The codes on the **cobas c** 111 system and on the Printer Tool must correspond.)

Version

The version uniquely identifies a particular set of application definitions.

The version number increases whenever there is a change to the application definitions, for example from version 1.0 to 1.1.

General definitions

3 Expand the **General** entry, select **Short Name**, and press [✎].

4 Change the short name (up to 5 alphanumeric characters) if required.

The short name affects the display of the test name in the user interface (for example test buttons, or test names in the orders and results lists, and in all printouts).

5 Press [»] and change the long name (up to 30 alphanumeric characters) of the test, if required.

The long name is a telling description of the test. It is particularly useful if the short name is not generally familiar in the laboratory environment.

6 Press [»] and then **On** to activate the application.

If an application is not active, its associated tests are not available for use. You cannot select them on the test selection screen. The application definitions remain on the system.

7 Press [»] and select the buttons of the tabs the test should be available from.

For details, see *Assigning tests to test tabs* on page B-119.

8 Press [✓] to confirm the definitions.

Calibration definitions

For Roche calibrators, recommended definitions are automatically defined for each application. You can change the sequence, interval, and the replicate value, if required.

Roche recommend not to change the calibration definitions of Roche reagents.

9 Expand the **Calibration** entry, select **Sequence**, and press [✎].

10 Change the sequence, if required. (The sequence values define when calibration becomes due, and the system automatically informs you about due calibrations.)

No Interval: The system does not inform you about the due status. Use this value if the reagent is stable enough over the whole period until it is empty and you replace it. Calibration is due whenever a new reagent set is loaded on the instrument.

Interval only: Performed when the reagent interval has expired.

Each Lot and Interval: Performed whenever the first reagent of a new lot is loaded and then each time the interval has expired.

Each set and Interval: Performed whenever a reagent is loaded or when the reagent interval has expired.

11 Change the interval (number of days, hours for ISE applications), if required.

12 Change the number of replicates, if required.

Possible values: 1, 2, 3. (The default value is 2.)

13 Press ⊘ to confirm the definitions.

Calibration definition changes require subsequent calibration of the tests.

Control definitions

14 Expand the **Control** entry, select **Sequence**, and press ✎.

15 Define the sequence.

Choose **No Interval** for cases when, for example, you intend to perform QC as part of standard sample testing and not as a separate task.

Choose **Interval Only** if QC should be performed whenever the reagent interval has expired. The system automatically informs you about due QCs.

16 Define the interval in hours.

17 For each control, perform the following steps:

- Define the material code.

  Unique identifier for the controls. Check the package insert of the control.

- Define whether QC should be performed after calibration of the test (**QC After Cal**).
- Define whether the test should have QC performed as part of the **Default QC** function.

  Default QC is an automated process for performing all QC measurements that are currently due. This is the ideal method if you want to perform QC periodically during routine operation

  On: QC will be performed collectively for all tests that use a certain control.

  Off: QC has to be ordered manually for each test.

18 Press ⊘ to confirm the definitions.

Ratio Calculation definitions

19 For applications that use a ratio, perform the following steps:

- Expand the **Ratio Calculation** entry, select **Coefficient w**, and press .
- Define one or two coefficients.
- Define the formula.

WARNING

Incorrect results due to inappropriate formula

The formula defines how the values of the applications and coefficients are mathematically combined to generate a result.

It is the responsibility of the user to ensure that the formula is appropriate for the application that is being defined.

20 Press to confirm the definitions.

Calculation definitions

21 Expand the **Calculation** entry, select **Factor**, and press .

22 Change the factor and offset, if correlating two different methods.

23 Choose whether valuation (a reference range) should be employed or not.

If you choose **Reference Range**, you need to define an upper and lower limit and decide which of them should be taken into account or whether both of them.

24 Define whether the lower limit is used, if required.

25 Define whether the higher limit is used, if required.

26 Change the lower limit value, if required.

27 Change the higher limit value, if required.

28 Define, for each control, whether sample results should be flagged that were generated using a test whose QC results were marked with a flag.

29 Press to confirm the definitions.

Result Conversion definitions

30 Expand the **Result Conversion** entry, select **Laboratory Unit**, and press .

31 Change the laboratory unit if you intend to work with units that are different from the currently specified units.

32 Type the conversion factor, if required.

This factor is required if lab units were defined.

33 Choose whether values should be displayed in standard or laboratory units.

This definition affects displays on screens as well as printouts.

34 Change the decimal position, if required.

This value corresponds to the number of digits after the decimal point that are displayed on the screens.

35 Press to confirm the definitions.

■

Uninstalling applications

Uninstalling an application means making the application unavailable for use in testing.

You can reinstall an uninstalled application.

See *Installing applications* on page B-137.

Before you can uninstall an application, you need to perform some preparation tasks:

► To prepare uninstalling an application

1 Delete all associated sample results.

See *Deleting sample results* on page B-94.

2 Delete all associated QC results, both from the **QC Status** list and the **QC History**.

See *Deleting QC results* on page B-96.

■

► To uninstall an application

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Select the application.

Select an application that is not in square brackets, for example ALTL. (Brackets indicate that the application is not currently installed.)

3 Press ⊖.

A confirmation screen is displayed.

4 Press ⊘ to confirm the action.

All associated calibration results and lot data are deleted.

In the applications list, the application name is enclosed in square brackets, for example [**GLU2**], and in the profile details, instead of the short name its application code is displayed.

The profiles that use this application are removed from the test selection screen. If you still want to use these profiles, you need to remove the application from them.

See *Removing tests from a profile* on page B-149.

■

Deleting applications

Deleting an application means removing the data from the system.

The process of removing an application from the system consists of the following steps:

1. Delete all associated sample results.
   See *Deleting sample results* on page B-94.
2. Delete all associated QC results, both from the **QC Status** list and the **QC History**.
   See *Deleting QC results* on page B-96.
3. Uninstall the application. This process makes the application unavailable for use in testing.
   See *Uninstalling applications* on page B-143.
4. Remove all associated reagent sets from any of the reagent disks. (The disk may be off board, and you might need to load it in order to remove the reagents.)
   See *To load the reagent disk* on page B-21
   See *Removing a reagent set* on page B-25.
5. Delete the application. This process removes the application data from the system.

► To delete an application

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Select the application.

3 Press ⊖.

The following table lists possible situations and how they affect the process of deleting.

Situation	Proceed as follows
There is one entry for the application in the list, and the application is currently installed (not in brackets).	1. Confirm to proceed with uninstalling. 2. In the applications list, select the uninstalled application (it is now contained in brackets). 3. Press ⊖. 4. Confirm to proceed with deleting the application.
There is one entry for the application in the list, and the application is currently not installed (in brackets).	Confirm to proceed with deleting the application.
There is a second entry for the application in the list. The selected application is installed (not in brackets)	Confirm to proceed with deleting the application. Note: You can only delete the installed application.
The selected item is a profile.	Confirm to proceed with deleting the profile.
There are still associated reagents on one of the disks.	Remove the associated reagent set from the disk. (The disk may be off board, and you might need to load it in order to remove the reagents.)

A confirmation screen is displayed.

4 Press ⊘.

The application data are deleted.

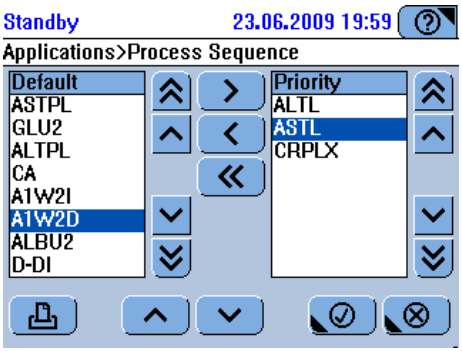
■

Defining the processing order

For a given sample, the tests are processed in the order defined by the time required to perform the tests (number of cycles), starting with the one that takes the longest. This order can be altered manually by defining a specific process sequence list.

► To define the processing sequence

1 Choose **Utilities** > **Applications** > **Process Sequence**.



2 In the **Default** list, select a test you want to be processed with high priority.

3 Press › to move it to the **Priority** list.

The tests are processed in the order displayed in this list. When the tests contained in this list are processed, the rest of the tests are processed in the normal order.

4 Perform steps 2 and 3 to move the other tests you want to process with high priority.

5 To move a test from the **Priority** to the **Default** list, select the test in the **Priority** list and press ‹. To move all tests to the **Default** lists, press «.

6 In the **Priority** list, select a test and use ^ and ˅ to move it up and down in the list.

7 Press ⊘ to save the processing sequence.

The processing sequence defined in the **Priority** list applies to all tests performed on the current **cobas c** 111 instrument.

■

Defining ratio applications

The user can manually define ratio applications. Such applications yield results that are mathematically arrived at, and are based on test results that were generated using up to four different applications.

In the results list, both the results of the test or tests as well as the calculated ratio result will be displayed.

► To define a ratio application

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Press ⊕.

3 Press **Add Ratio**.

4 Type the code and press ».

The code is a number between 910 and 930 and identifies the application.

5 Type the short name and press ».

The short name must be unique on the **cobas c** 111 system and consists of up to 5 alphanumeric characters. It is used on the screens, for example on the test selection screen or the results list.

6 Type the long name and press ».

The long name must be unique on the **cobas c** 111 system and consists of up to 30 alphanumeric characters. Use a name that is commonly known in your laboratory environment.

7 Select the first application and press ».

You can define between one and four applications.

8 Define the other applications, if required.

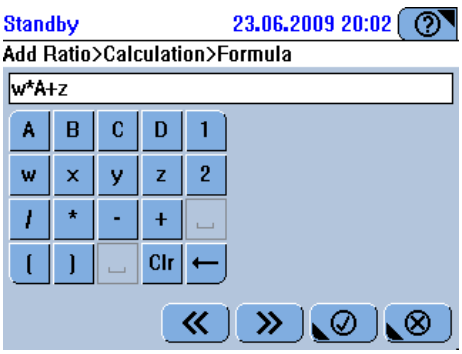
9 Type the first coefficient and press ».

You can define between one and four coefficients.

10 Define the other coefficients, if required.

11 Type the formula and press ».

The formula relates the applications with the coefficients. You can use the following operands: +, -, *, /, (,), space, and application subindex 1 and 2.



WARNING

Incorrect results due to inappropriate formula

The formula defines how the values of the applications and coefficients are mathematically combined to generate a result.

It is the responsibility of the user to ensure that the formula is appropriate for the application that is being defined.

12 Type the factor to compensate for differences in measuring methods of different instruments, then press [»].

13 Type the offset and press [»].

14 Select whether the offset/correlation factor is going to be used or not, then press [»].

15 Select the valuation type, then press [»].

No valuation means that no valuation will be performed.

Reference range means that the result will be compared with the defined reference ranges.

16 Select whether the low range will be used or not, then press [»].

17 Select whether the high range will be used or not, then press [»].

18 Type the low limit, then press [»].

19 Type the high limit, then press [»].

20 Type the standard unit, then press [»].

21 Type the laboratory unit, then press [»].

22 Type the conversion factor, then press [»].

23 Select whether the standard or the laboratory unit will be displayed for the final ratio result, then press [»].

(For the calculation of the individual results, the system uses standard units.)

24 Type how many decimal positions will be used in the displayed results.

25 Press [✓].

■

Profiles

Defining profiles

A profile is a set of tests that are frequently ordered in combination. When ordering a profile all tests of the profile are performed.

► To define a profile

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Press ⊕.

3 Press **Add Profile**.

4 Type the profile code. (For customer defined profiles, use the numbers 910 through 930.)

5 Type the short name (up to 5 characters).

The short name will appear on the test selection screens.

6 Type the long name (up to 30 characters).

7 Select the tests that should be included in the profile.

8 Press ✓ to confirm the selection.

■

Adding tests to a profile

► To add tests to a profile

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Select the profile.

3 Expand the entry.

4 Expand the **General** entry.

5 Select **Applications**.

6 Press ✎.

A test selection screen is displayed.

7 Select the tests.

8 Press ✓ to confirm the selection.

👁 For information on assigning a profile to tabs on the test selection screen, see *Assigning tests to test tabs* on page B-119.

■

Removing tests from a profile

► **To remove tests from a profile**

1 Choose **Utilities** > **Applications** > **Laboratory Parameters**.

2 Select the profile.

3 Expand the entry.

4 Expand the **General** entry.

5 Select **Applications**.

6 Press [✎].

A test selection screen is displayed.

7 Clear the selection of the tests you want to remove.

8 Press [✓] to confirm the selection.

■

Deleting profiles

👁 See *Deleting applications* on page B-144.

Defining control definitions and lots

➔ **Workplace** > **Lot Data**

► **To define control definitions and lots**

Perform the following steps for all controls.

1 Choose **Workplace** > **Lot Data**.

2 Press **Controls**.

A screen is displayed that lists all installed control lots.

3 Press [⊕].

A screen is displayed, asking you to scan the barcode transfer sheet or to type the data manually.

4 Define the lot values.

Do one of the following:

If…	Do this…
The lot data are available from a barcode	1. Scan the barcode. The screen is displayed again that lists all installed control lots. The new lot is selected.
You want to type the data manually	1. Press ⌨. 2. Type the name and press ». 3. Type the material code and press ». You find this code in **Utilities** > **Applications** > select a test > ✎ > **Control**. 4. Type the Lot ID and press ». 5. Type the expiration date. Use the date format as indicated on the screen. 6. Press ✓ to confirm the definitions. If a lot with the same ID already exists on the system, a screen is displayed, asking you whether you want to replace the existing lot. Press ✓ to confirm the definitions. 7. Press ***Add new test***. 8. Press ⊕. A screen is displayed that contains all tests that use this control and that have not yet been assigned to this lot. 9. Select a test and press ». 10. Type the value for the mean concentration and press ». 11. Type the value for the standard deviation. 12. Press ✓ to confirm the definitions. The screen for handling control lot data is displayed again. 13. Perform steps 7 through 12 for all tests you want to use.

■

Defining calibrator definitions and lots

You need to perform the definitions for all calibrators.

► To define a calibrator lot

1 Choose **Workplace** > **Lot Data**.

2 Press **Calibrators**.

A screen is displayed that lists all installed calibrator lots.

3 Press ⊕.

A screen is displayed, asking you to scan the barcode or to type the data manually.

4 Define the lot values. Do one of the following:

If…	Do this…
The lot data are available from a bar-code	1. Scan the barcode. The screen is displayed again that lists all installed calibrator lots. The new lot is selected.
You want to type the data manually	1. Press ⌨. 2. Type the name (up to 10 alphanumeric characters) and press ». 3. Type the material code and press ». Refer to the package insert. 4. Type the lot ID (up to nine alphanumeric characters) and press ». 5. Type the expiration date and press ». Use the date format as indicated on the screen. 6. Type the number of calibrators (cups) you need to place on the instrument. Use the information given on the package insert. (Exclude calibrators that use system water from this number. See step 14.) 7. Press ✓ to confirm the definitions. 8. Press ***Add new test***. 9. Press ⊕. A screen is displayed that shows all tests that have this calibrator defined for them and that are not yet assigned to this lot. 10. Press one of the test buttons. 11. Press ». 12. Define the first calibration value (target value). 13. Define the next calibration value. You can define up to six calibration values, and you must define them in descending order. 14. Select the value for **Last is Water**. Press **On** if you want to calibrate with system water as zero calibrator. (In this case, no cup needs to be placed on the system. (See step 7). Press **Off** if you want to use a special zero calibrator for the calibration. (The special zero calibrator needs to be placed on the sample area.) 15. Press ✓ to confirm the definitions.

Calibration values (target values) in method sheets may be defined in increasing order of concentration. Always define the values in *decreasing* order on the **cobas c** 111 instrument.

■

Short guide to application definitions

The following tables provide reference information on the meaning and use of application definitions the user might want to change.

Version

The version uniquely identifies a particular set of application definitions.

Code

The Roche application code identifies the application. If you work with a LIS you may need to map the Roche application code with your own code. All applications, profiles, and ratios must be identified with an application code. For profiles and ratios, use a number between 910 and 930 for these codes.

See *Mapping the host codes* on page B-162.

This code is also used on the **cobas c** 111 Printer Tool. (The codes on the **cobas c** 111 system and on the Printer Tool must correspond.)

General application definitions

Item	Values	Comment
Short Name	Up to 5 alphanumeric characters	The short name is used on the screens, for example on the test selection screen or the results list.
Long Name	Up to 30 alphanumeric characters	The long name is a telling description of the test. It is particularly useful if the short name is not generally familiar in the laboratory environment.
Active	**On**, **Off**	Tests that not active are not available for use. You cannot see them on the screens. Their application definitions remain on the system.
Test Tabs	See *Workflow definitions* on page B-164.	Choose one or several of the buttons. The test will be included in the corresponding test tabs. Choose **Easy** if you work with order mode **Easy**. Clear all selections to prevent the test from being selected in the test selection screens.

Table B-12 General application definitions

Calibration definitions

ISE applications do not have calibration definitions.

Item	Values	Comment
Sequence	The sequence values define when calibration becomes due, and the system automatically informs you about due calibrations.	
	No Interval	The system does not inform you about the due status. Use this value if the reagent is stable enough over the whole period until it is empty and you replace it. Calibration is due whenever a new reagent set is loaded on the instrument.
	Interval Only	Due whenever the reagent interval has expired.
	Each Set and Interval	Due whenever a new reagent is loaded and when the interval has expired. The interval starts again whenever you place a new reagent set. You can turn off the interval check by defining its duration as 0 (zero).
	Each Lot and Interval	Due whenever the fist reagent of a new lot is loaded and then each time the interval has expired. The interval (re)starts whenever you calibrate a reagent set. You can turn off the interval check by defining its duration as 0 (zero). If you install a reagent set of the same lot, no calibration is required. (The system uses the Lot calibration result as the Set calibration result of the new reagent set.)
Interval	Number of days. (For ISE, 1 day fixed.)	Use 0 (zero) if the **Sequence** is set to **No Interval**.
Replicates	1, 2	Number of times each measurement should be repeated.

Table B-13 Calibration definitions

Control definitions

Item	Values	Comment
Sequence	**No Interval**	The system does not inform you about the due status. Use this value if you intend to perform QC as part of standard sample testing and not as a separate task, and if QC should be handled by a host computer. Note that an accepted QC result is required for a test before it can be used.
	Interval Only	Due whenever the reagent interval has expired. The system automatically informs you about due QCs.
Interval	Number of days (hours for ISE applications)	Use 0 (zero) if the Sequence is set to **No Interval**.
For each of the controls:		
Mat. Code	0 ... 999	Unique identification of the control material. Numbers 801 through 999 are reserved for non Roche controls. You need to define this initially for every application.
QC After Cal	**On, Off**	QC needs to be performed after each calibration of the test.
Default QC	**On, Off**	Mark the test to have QC performed as part of the **Default QC** function. **Default QC** is an automated process for performing all QC measurements that are currently due. This is the ideal method if you want to perform QC periodically during routine operation.

Table B-14 Control definitions

Calculation definitions

Item	Values	Comment
Factor		Used for sample and control results. Final result = (result * **Factor**) + **Offset** The correlation factor is used to compensate for differences in measuring methods of different instruments. By applying a factor, the final results of the different instruments can be directly compared.
Offset		The offset is used to compensate for differences in measuring methods of different instruments. By adding the offset, the final results of the different instruments can be directly compared.
Valuation	**No Valuation**	
	Reference Range	Use the limits defined as **Low Limit** and **High Limit**.
Low Used	**On**, **Off**	Refers to **Low Limit**.
High Used	**On**, **Off**	Refers to **High Limit**.
Low Limit		Results that are outside the limit are flagged.
High Limit		Results that are outside the limit are flagged.
1...3:Flag QC Fail	**On**, **Off**	Choose **On** to ensure that all sample results are flagged that were generated using a test whose QC results were marked with a flag. The initial number refers to the control that was used for performing the QC. (See also *Control definitions*.)

Table B-15 Calculation definitions

Calculation definitions (ratio applications)

Item	Values	Comment
Application A through D	Up to 5 alphanumeric characters	Short names of the installed applications.
Coefficient w through z	000 … 999	Numeric variable for use in the formula.
Formula	Defined application and coefficient letters.	The formula relates the defined applications with the coefficients.
	Operands: +, -, *, /, (,), and space	For example: (A * w + B) * A / B

Table B-16 Calculation definitions for ratio applications

Laboratory correlations (ratio applications)

Item	Values	Comment
Factor		Used for sample and control results. Final result = (result * **Factor**) + **Offset** The correlation factor is used to compensate for differences in measuring methods of different instruments. By applying a factor, the final results of the different instruments can be directly compared.
Offset		The offset is used to compensate for differences in measuring methods of different instruments. By adding the offset, the final results of the different instruments can be directly compared.
Used	**On**, **Off**	Choose **On** to ensure that the defined factor and offset are applied the final ratio result.

Table B-17 Laboratory correlation definitions for ratio applications

Reference range definitions (ratio applications)

Item	Values	Comment
Valuation	**No Valuation**	No valuation is performed by the system.
	Reference Range	Use the limits defined as **Low Limit** and **High Limit**.
Low Used	**On**, **Off**	Refers to **Low Limit**.
High Used	**On**, **Off**	Refers to **High Limit**.
Low Limit	Values in standard units.	Results that are outside the limit are flagged.
High Limit	Values in standard units.	Results that are outside the limit are flagged.

Table B-18 Reference range definitions for ratio applications

Result conversion definitions

Item	Values	Comment
Standard Unit		
Laboratory Unit	Alphanumeric characters	Type the unit.
Factor		Conversion factor for converting results from one unit to another, for example from mg/dL to mmol/L.
Displayed Unit	**Standard Unit**	
	Laboratory Unit	
Dec. Position	0 ... 4	Number of digits after decimal point that are displayed on the screens.

Table B-19 Result conversion definitions

Configuration

Changing your password

NOTICE

Damage to data and programs due to unauthorized access to the cobas c 111 instrument

User access to the **cobas c** 111 instrument is controlled by a login name and password. Users are administered by a system administrator.

Roche recommend to periodically change the password of the system administrator and to store the current password in a safe place with adequate access control.

User name and password are case sensitive. This means that for example Admin and admin are two different names.

► To change you password

1 Do one of the following:

If…	Do this…
You are logged off:	1. Press **Log On**.
You are logged on:	1. Press the button showing your user name. 2. Press **Log On**.

2 Type your user name.

As soon as you type the first characters of your user name, the system looks for a name that starts with these letters and, if it finds one, displays the complete name.

3 Press ✓.

4 Press **Change Password**.

5 Type your old password.

6 Press ✓.

7 Type the new password

8 Press ✓.

9 Type the new password a second time.

10 Press ✓.

■

Scheduling maintenance actions

The **cobas c** 111 instrument facilitates performing the maintenance actions in bundles at times that suit your laboratory work processes. To that purpose, you can define one day of the week as your maintenance day.

Concept of the main maintenance day

The main maintenance day is the day in the week when you want to perform the majority of the maintenance actions.

Let us suppose that you chose Monday as your main maintenance day. On the Maintenance screen, actions that are due on Monday or an earlier day are marked in red, actions that will fall due between Tuesday and Sunday will be marked in yellow.

The idea is to perform on the main maintenance day all red and yellow maintenance actions. This way, between Tuesday and Sunday, you only need to perform maintenance that need to be performed daily.

► To define the main maintenance day

1. Choose **Utilities** > **Configuration** > **Maintenance**.
2. Expand the main entry and select **Major Maint. Day**.
3. Press [✎].

   A screen is displayed for selecting a day of the week.
4. Press one of the weekday buttons.
5. Press [✓].

■

The definition of the minor maintenance day has currently no practical influence on the maintenance scheduling, because there are no maintenance actions with intervals of between two and six days.

Handling user interface language

You can choose from up to six languages. (You could install more than six languages, but only the first six in the alphabetic sequence are available for selection.)

In the software and the user interface, the languages are identified by their two-letter abbreviation (ISO 639-1). The following languages are available:

Abbreviation	Language	Abbreviation	Language
DE	German	EL	Greek
EN	English	ES	Spanish
FI	Finnish	FR	French
HU	Hungarian	ID	Indonesian
KO	Korean	PL	Polish
PT	Portuguese	TR	Turkish
ZH	Chinese		

Table B-20 Abbreviations for user interface languages

Prerequisites
- Make sure that there are no pending or unfinished orders.
- The system must be in **Standby** status.
- You need **Lab Manager** or **Administrator** user rights.

► To install a new language

1. Copy the language file (c111_xx.tar, where xx is the language code) to the Root directory of a USB stick.
2. Choose **Utilities** > **Import**.
3. Press **Software**.

   A screen is displayed, asking you whether you want forced download of controller software, that is whether you want to overwrite the current controller firmware irrespective of its current status.
4. Press ⊗ to perform standard import.

   A screen is displayed, asking you to insert the USB stick.
5. Insert the USB stick.
6. Press ✓.

   A screen is displayed that shows the file structure on the stick.

   You should see the c111_xx.tar file, where xx stands for the language abbreviation, for example **c111_en.tar** represents the English language file.
7. Select the c111_xx.tar file.
8. Press ✓ to confirm the selection.

   The software is installed on the system. A message will inform you when the installation is complete.
9. When the installation is complete, remove the USB stick.

   For the language to become active you need to restart the system.
10. Press ⏻.
11. Press **Restart**.

    The system will shut down and automatically restart.

    When startup is complete, the **Overview** tab is displayed, and the system is in **Standby** status.
12. Wait until the system is in **Standby** status.

■

► To change the user interface language

1. Choose **Utilities** > **Configuration** > **System**.
2. Expand the list.
3. Select **Language**.
4. Press ✎.

   A screen is displayed that contains a button for each of the currently installed languages. The buttons are labelled with the two-letter language abbreviation.

   👁 See Table B-20 on page B-158.

5 Press the button for the required language.

6 Press ✓.

For a language to become active you need to restart the system.

7 Press ⏻.

8 Press **Restart**.

The system will shut down and automatically restart.

When startup is complete, the **Overview** tab is displayed, and the system is in **Standby** status.

9 Wait until the system is in **Standby** status.

■

Uninstalling a language

You can uninstall all languages except English.

Prerequisites

- The current user interface language must be English.
  👁 See *To change the user interface language* on page B-159.
- The system must be in **Standby** status.
- The uninstall language file **c111_uninstall_languages.tar** has been copied to a USB stick.
- You need **Lab Manager** or **Administrator** user rights.

► To uninstall user interface languages

1 Choose **Utilities** > **Import**.

2 Press **Software**.

A screen is displayed, asking you to insert the USB stick.

Insert the USB stick.

3 Press ✓.

A screen is displayed that shows the file structure on the stick.

4 Select the **c111_uninstall_languages.tar** file.

5 Press ✓ to confirm the selection.

All languages except English are deleted from the system. A message will inform you when uninstalling is complete.

6 When the installation is complete, remove the USB stick.

■

User management

You need **Administrator** user rights to define or delete a user.

Defining a user

► To define a user

1 Choose **Utilities** > **Users**.

A screen is displayed that lists all currently defined users.

2 Press ⊕.

3 Type the user name.

Make sure it is unique within your laboratory.

4 Press ».

5 Type the password.

6 Press ».

7 Press the appropriate user level button.

- Press **Operator** for users who should perform routine tests.
- Press **Supervisor** for users who should perform routine tests as well as calibration and QC.
- Press **Lab Manager** for users who should perform all test actions and who should be able to update or add applications and perform diagnostics tasks.
- Press **Administrator** to define the administrator of the **cobas c** 111 instrument. The administrator can, in addition to all **Lab Manager** actions, perform user administration.

8 Press ✓.

■

Deleting a user

► To delete a user

1 Choose **Utilities** > **Users**.

A screen is displayed that lists all currently defined users.

2 Select the user you want to delete.

3 Press ⊖.

A confirmation screen is displayed.

4 Press ✎ to confirm the deletion.

■

Editing the acceptable flags list

When working with automatic accepting of results, results that are not flagged are automatically accepted. Results with flags that are marked in an acceptable flags list are accepted as well. There is such a list for sample, QC, and calibration results.

► To add or remove a flag from an acceptable flags list

1. Choose **Utilities** > **Configuration** > **Result Handling**.
2. Expand the list.
3. Select one of the following entries:
   - **Sample Accept. Flags**
   - **QC Acceptable Flags**
   - **Cal Acceptable Flags**
4. Press .

   A list of relevant flags is displayed.
5. Press the square to the left of a flag name to select it or to cancel its selection.

   A selected flag shows a check mark (✓).
6. Press .

■

Mapping the host codes

Applications are delivered with a unique ID called code. Laboratories often use their own codes for applications. By mapping the codes used by the laboratory (host codes) to those defined by the application manufacturer, the laboratory can work with their own accustomed codes. The **cobas c** 111 instrument provides a mapping table that can easily be edited.

The application, profile and ratio codes are also used on the **cobas c** 111 Printer Tool. (The codes on the **cobas c** 111 system and on the Printer Tool must correspond.)

Editing a mapping table involves the following steps:

1. Exporting the mapping table to an USB stick. (The table is written as a text file.)
2. Editing the file on a computer and save it as a text file to the stick.
3. Importing the file to the **cobas c** 111 instrument.

► To export the mapping table

1. Choose **Utilities** > **Applications** > **Host Codes**.
2. Press .

   A screen is displayed, asking you to insert the USB stick.
3. Insert the USB stick.
4. Press .
5. Select the directory where you want to save the mapping file.

6 Press ⊘ to confirm the selection.

The file is exported as a text file of the name format hct_yyyymmddhhmmss.txt.

■

► To re-import the mapping table

1 Choose **Utilities** > **Host Codes**.

2 Press ⇦.

A screen is displayed, asking you to insert the USB stick.

3 Insert the USB stick.

4 Press ⊘.

5 Select the mapping file.

Typically, mapping files have the name format hct_yyyymmddhhmmss.txt.

Press ***.txt** to display text files only.

Press *.* to display all files and directories.

6 Press ⊘ to confirm the selection.

The file is installed on the system. The screen with the mapping table is displayed again.

■

► To use the manufacturer's application codes

1 Choose **Utilities** > **Host Codes**.

2 Press 1:1.

The host codes are set to values that are identical to the application codes.

By pressing 1:1 again, you can revert to the original values.

■

Short guide to configuration definitions

Workflow definitions

Item	Values	Comment
Working Mode		Defines the way in which you select tests during order definition.
	Manual	Use this definition if the **cobas c** 111 instrument is used as a stand-alone system. During order definition, the test selection screen is displayed, allowing you to select the tests or to make changes to the selection.
	Host	Use this definition if the **cobas c** 111 instrument is connected to a host computer or to a computer running the **cobas c** 111 Printer Tool. The orders are automatically defined, the test selection screen is not displayed. After identifying the sample, you are asked to place the sample.
Sample Barcode	**On**, **Off**	You can work with or without barcodes on sample tubes. Use **Off** only if you exclusively work without barcodes. If you use **On**, during order definition the option to type the sample ID manually is skipped
Order Mode	**Easy**	You work with one test panel on the test selection screen, containing up to 25 tests. Typical situation for this mode: You work with one or two reagent disks, manual order identification, identical sample and order IDs, possibly but not necessarily with host connection.
	Full	You can work with up to six test tabs on the test selection screen, each containing up to 20 tests. Typical situation for this mode: You distribute the reagents across several (up to eight) reagent disks and you predominantly work with specific groups of tests, for example for emergency situations or for testing diabetes. You also work with a host connection with automatic order identification and result upload.
Sample ID Handling	**Order ID = Sample ID**	The order ID is automatically defined when you identify the sample.
	Independent IDs	You define the sample ID and order ID independently of each other.
	Grouped Sample ID	Order and sample ID are identical. For a given sample, the same sample ID is used all the time. A three digit number is appended and automatically increased with each new order. Examples: 789-001 for the first order, 789-002 for the second order, and so on.

Table B-21 Workflow definitions

Item	Values	Comment
Sample ID Separator	One alphanumeric character	This definition is used in combination with **Grouped Sample ID**. It defines the character that separates the sample ID from the automatically appended number. Examples: 789-001, 789.001, 789_001.
Auto Order-ID	**On**, **Off**	If you use **On**, the system automatically increments the order ID number by one whenever you define a new order. If you use **On**, choose **Off** for **Order ID = Sample ID**.
Auto Print Results	**On**, **Off**	If you use **On**, sample results are printed as soon as all results of the order are available and accepted.
Test Tab 1... 6 Name	Up to four alphanumeric characters	Display name for the test tab 1... 6 Test tabs are used to group tests that are usually used together. You can assign a test to more than one tab.
Test Tab 1... 6 Visible	**On**, **Off**	Use **On** to make available the tab on the test selection screen.

Table B-21 Workflow definitions

Host definitions

Item	Values	Comment
Baud Rate		Data transmission rate for host interface communication. Select one of the predefined values.
Handshake	**Off**	An exchange of signals between two devices when communication begins in order to ensure synchronization.
	Hardware	
	XON/XOFF	
Line Mode		Number of bits and stop bits used during data transmission. Select one of the predefined values.
Parity Check	**On**, **Off**	An error detection technique that tests the integrity of digital data in memory or on disk.
Communication Mode	**Off**	Download to the **cobas c** 111instrument is possible, but upload to host is not.
	Batch	Only manual upload to the host is possible.
	Realtime	Results and queries are sent during processing.
Checksum	**On**, **Off**	A value used to ensure that data are stored or transmitted without error. It is stored with the data. When the data are retrieved from memory or received at the other end of a network, a new checksum is computed and matched against the existing checksum. A non-match indicates an error.

Table B-22 Host definitions

Item	Values	Comment
Order Query Mode		Query mode allows real-time communication during order definition of regular, rerun, and repeated tests.
	Off	No queries are sent. Test orders have to be defined either manually or by downloading them from the host.
	Once	A query is sent only when the sample is identified the first time.
	Always	A query is sent every time the sample is identified.
Timeout	10 ... 300 s	Period of time the system will wait for a response from the host when working in **Order Query Mode**. This definition applies to routine, STAT and rerun sample tests.
Send Result Mode	**Off**	The results are sent to the host manually.
	Complete	The results are automatically sent to the host when all results of the order are available and accepted.
	Immediate	Each result is automatically sent to the host as soon as it has been accepted.
Send Raw Data	**On**, **Off**	Raw data include all measurement results made during the measuring cycles, not just the calculated test results.
Trace	**On**, **Off**	The Trace function records the content of the communication with the host in a trace file. This is a troubleshooting function. Do not work with it during normal daily operation. The trace file can be exported as a log file (**Utilities** > **Export** > **Log Files**; file format: htryyyymmddhhmmss.log.)
System Device ID	Up to 10 alphanumeric characters.	The ID is used on reports and for communication between the **cobas c** 111 instrument and the host.
Host Device ID	Up to 10 alphanumeric characters.	The ID is used on reports and for communication between the **cobas c** 111 instrument and the host.

Table B-22 Host definitions

Result handling

Item	Values	Comment
Sample Auto Accept	**On**, **Off**	Results that do not contain a flag are automatically accepted. Results with flags that are marked in a list of acceptable flags are accepted as well.
Sample Accept. Flags		List of possible flags. Results with marked flags are automatically accepted if **Sample Auto Accept** is on.
QC Auto Accept	**On**, **Off**	Results that do not contain a flag are automatically accepted. Results with flags that are marked in a list of acceptable flags are accepted as well.
QC Acceptable Flags		List of possible flags. Results with marked flags are automatically accepted if **QC Auto Accept** is on.
Cal Auto Accept	**On**, **Off**	Results that do not contain a flag are automatically accepted. Results with flags that are marked in a list of acceptable flags are accepted as well.
Cal Acceptable Flags		List of possible flags. Results with marked flags are automatically accepted if **Cal Auto Accept** is on.

Table B-23 Result handling definitions

Calibration

Item	Values	Comment
Forecast Hours	0 ... 999 h	Calibrations that fall due within this period will be performed collectively. 0 means working without this feature. The default value is 8.

Table B-24 Calibration definitions

QC

Item	Values	Comment
Rule 1		Rule: A flag is generated if one result is outside a limit. s : Standard deviation. The value for the standard deviation is defined in the QC lot.
	Off	
	2.5s	
	3s	
Rule 2		Rule: A flag is generated if two consecutive results are outside the same limit. s : Standard deviation. The value for the standard deviation is defined in the QC lot.
	Off	
	2s	

Table B-25 QC definitions

System

Item	Values	Comment
Language	Language ID according to ISO 639-1. See Table B-20 on page B-158.	The language English is always included. Choose one of the available languages. (The first five languages in the alphabetical sequence of the installed languages and English are displayed.)
Date Format	dd.mm.yyyy dd-mm-yyyy yyyy.mm.dd yyyy-mm-dd mm/dd/yyyy	Examples for June 14, 2006: • dd.mm.yyyy: 14.06.2006 • mm/dd/yyyy: 06/14/2006
Time Format	**24 Hours** **12 Hours**	
Screen Saver Wait	0 ... 120 min	Time after which the screen saver feature becomes active. 0 (zero) means that the screen saver function is off. The screen saver time is linked to the **Auto Log-off** feature. For example, if you define a Screen Saver Wait time of 5 minutes, then after 5 minutes of inactivity, the screen saver feature becomes active and the user is automatically logged off, provided **Auto Log-off** is on.
Auto Log-off	**On**, **Off**	If you work with **On** the user is automatically logged off after a certain number minutes of inactivity on the instrument. This number is defined in the **Screen Saver Wait** definition.
Sound Effects	**On**, **Off**	Acoustic signals when handling instrument items, e.g. clicking sound when typing. (Does not affect the acoustic signals for alarms and warnings.)
Volume	0 ... 100	Volume of *any* acoustic signal generated by the instrument, including alarm and warning signals. 0 (zero) means silent.
Host Server	**On**	The host interface of the instrument is enabled, allowing it to communicate with a host.
	Off	The host interface of the instrument is disabled. Communication with a host computer is not possible. Host definitions have no effect.

Table B-26 System definitions

Date and time

Item	Values	Comment
Date	Format: dd.mm.yyyy	Date that is used for time records, for example with results. Example: 17.02.2006 for February 2, 2006. This format is for entry purposes only. It does not influence the format of displayed dates.
Time	Format: hh:mm	Time that is used for time records, for example with results. Example: 08:32. This format is for entry purposes only. It does not influence the format of displayed times.

Table B-27 Date and time definitions

Maintenance

Item	Values	Comment
Major Maint. Day		Day in the week when you usually perform maintenance actions.
Minor Maint. Day		This definition has currently no effect.

Table B-28 Maintenance definitions

Abs adjustment

The absorbance adjustment values cannot be changed.

Item	Values	Comment
Adjustment Valid	**On, Off**	
H2O Signal		For each wave length, the adjustment value for the cuvette filled with water is given.
H2O Cuv Signal		For each wave length, the adjustment value for the empty cuvette is given.

Table B-29 Absorbance adjustment definitions

Defining extra wash cycles

Extra wash cycles are used to minimize carry-over.

You can define an extra wash cycle either by reading a barcode or by defining the values manually.

► To define an extra wash cycle

1 Choose **Utilities** > **Applications** > **Extra Wash Cycles**.

A screen is displayed that lists the currently defined extra wash cycles.

2 Select **Add new rule**.

3 Press ⊕.

4 Do one of the following.

If…	Do this…
The definitions are available on a barcode:	1. Read the barcode. The definitions will be installed on the system.
You want to define the values manually:	1. Press ⌨. 2. Choose when—in relation to the pipetting action from the bottle defined in **Trigger Bottle Code** and **Pipetting Type**—the extra wash cycle should be performed (action), then press ». 3. Type the trigger-bottle code and press ». The trigger-bottle code is the reagent set code. You find it on the barcode sheet. 4. Choose the pipetting type. This defines the individual bottle (bottle of the set or the sample tube) whose pipetting triggers performance of the extra wash cycle. 5. Define whether the wash cycle should be active or not. 6. Type the cleaner bottle code to define which cleaner should be used. 7. Type the volume of cleaner in µL that will be pipetted. 8. Press ✓ to confirm the definitions.

The new wash cycle is listed in the **Extra Wash Cycles** list. Its name is made up of the action, the short name of the trigger bottle and the pipetting type.

■

Activating, deactivating and deleting extra wash cycles

You can deactivate an extra wash cycle if you do not want to use it. (The definitions remain on the system. You can activate the extra wash cycle later again.)

To ensure the highest effectiveness of probe cleaning, extra wash cycles are performed automatically by the **cobas c** 111 instrument when using development channel applications.

Roche strongly recommends to always use extra wash cycles with development channel applications, and also to always load extra cleaner when tests with extra wash cycles are used.

Roche Diagnostics Ltd. assumes only limited liability when using the **cobas c** 111 instrument in conjunction with the **cobas c** 111 Development Channel Programming Software.

For detailed information on this matter refer to the latest version of the Development Channel Registration Form **cobas c** 111 and the **cobas c** 111 Development Channel Operator's Manual.

► To activate or deactivate an extra wash cycle

1 Choose **Utilities** > **Applications** > **Extra Wash Cycles**.

A screen is displayed that lists the currently defined extra wash cycles.

2 Select and expand the extra wash cycle entry.

3 Press .

4 Choose **On** to activate the extra wash cycle.

Choose **Off** to deactivate the extra wash cycle.

5 Press .

A screen is displayed for entering your password.

6 Type your password and confirm by pressing .

■

► To delete an extra wash cycle

1 Choose **Utilities** > **Applications** > **Extra Wash Cycles**.

A screen is displayed that lists the currently defined extra wash cycles.

2 Select the extra wash cycle entry.

3 Press .

A screen is displayed for entering your password.

4 Type your password and confirm by pressing .

The extra wash cycle definitions are deleted.

■

Short guide to extra wash cycle definitions

➔ Utilities > Applications > Extra Wash Cycles >

Extra wash cycle definitions

Item	Values	Comment
Active	**On**, **Off**	Defines whether the extra wash cycle can be applied or not.
Action	**None** **Before** **After**	Defines when, in relation to the pipetting action from the bottle defined in **Trigger Bottle Code** and **Pipetting Type**, the extra wash cycle should be performed.
Trigger-Bottle Code	0 ... 999	Bottle set code of the fluid that triggers performance of the extra wash cycle. If you use the pipetting type **Sample**, it defines the bottle whose fluid will be prevented from being carried over to the sample by using the extra wash cycle.
Pipetting Type	**Reagent 1** **Reagent 2** **Start Reagent** **Sample**	Defines the individual bottle (bottle of the set or a sample tube) whose pipetting triggers performance of the extra wash cycle.
Cleaner-Bottle Code	0 ... 999	Material code of the cleaner.
Volume	µL	Amount of cleaner that will be pipetted during the extra wash cycle.

Table B-30 Extra wash cycle definitions

Short guide to reagent mixing rules

➔ **Utilities** > **Applications** > **Reagent Mixing** > [edit]

You can import and delete mixing rules, but cannot change them.

For importing reagent mixing rules, see *Importing automatic mixing and extra wash cycle definitions* on page B-116.

Reagent mixing rule definitions

You cannot change these definitions.

Item	Values	Comment
Active		Defines whether this rule can be applied to an application or not.
Initial Mixing Time		Defines the duration of the mixing for the first mixing.
Mixing Interval		Defines the time after which mixing must be performed again.
Periodic Mixing Time		Defines the duration of the mixing for the second or subsequent mixing.
Relaxing Time		Defines the time after mixing before the reagent can be used.

Table B-31 Reagent mixing rule definitions

Printing mixing rules

You can print mixing rules.

► **To print mixing rules**

1 Choose **Utilities** > **Applications** > **Reagent Mixing**.

2 Select the mixing rule you want to print.

3 Press [OK].

A printing screen is displayed.

4 Select whether you want to print the selected rule set or all defined rule sets.

The rules are printed on the built-in printer.

■

Deleting mixing rules

Prerequisites You need **Lab Manager** or **Administrator** user rights to perform this task.

► **To delete a mixing rule**

1 Choose **Utilities** > **Applications** > **Reagent Mixing**.

A screen is displayed that lists the currently defined mixing rules.

2 Select the mixing rule.

3 Press ⊖.

A screen is displayed for entering your password.

4 Type your password and confirm by pressing ✓.

The mixing rule definitions are deleted.

■

Maintenance C

8 General maintenance C-3

General maintenance

Keeping the instrument going

In this chapter, you will find step-by-step instructions of the maintenance actions that you must perform to keep the instrument running smoothly and efficiently.

In this chapter *Chapter* **8**

Overview C-5
Performing maintenance actions C-6
Maintenance actions and their intervals C-7
Maintenance actions C-8
Safety information C-8
Deproteinize the probe C-10
Prime the fluid system C-11
Clean the probe manually C-12
Clean reagent disk and sample area C-14
Clean the water and waste containers C-16
Replace water inlet filter C-19
Clean and disinfect housing C-21
Clean up the database C-23
Replace photometer lamp C-24
Contact service representative C-27
Perform an air/water calibration C-28
Initialize degasser fluid sensor C-30
Clean rotor and heating channel C-32

Overview

Completing maintenance actions correctly and on time helps to ensure smooth and uninterrupted operation of your instrument.

Maintenance scheduling

The **cobas c** 111 instrument facilitates performing the maintenance actions in bundles at the times that suit your laboratory work processes. To that purpose, you can define in the configuration settings one day of the week as your maintenance day.

For information on scheduling maintenance actions, see *Scheduling maintenance actions* on page B-158.

All maintenance actions can be performed any time.

Interval

For most maintenance actions a fixed maintenance interval is defined. (You cannot change this interval.) This is the basis upon which the system calculates the date when the actions need to be performed.

The interval timers and counters are reset whenever you confirm that the maintenance action has been performed.

Maintenance actions without predefined intervals are performed whenever necessary, or they are triggered by another maintenance action.

Due date

The due date is the last possible maintenance day. This is the date you see when you check the status of maintenance actions.

Ensuring smooth operation

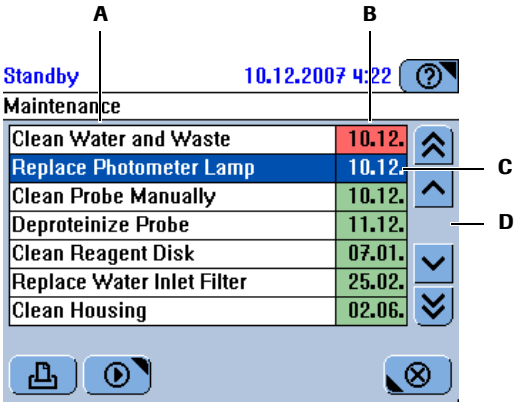
Performing all due maintenance actions during the daily **Prepare** or **End Shift** phase ensures that routine operation does not have to be interrupted for performing maintenance actions.

Performing maintenance actions

► To perform maintenance actions

Checking when maintenance actions are due

1 Choose **Utilities** > **Maintenance**



A Maintenance action name.
B Due dates, in ascending order.
C This maintenance action is selected.
D Use the scroll bar to display the maintenance actions that are currently hidden.

Figure C-1

Interpreting the colors

	The defined maintenance interval has expired. Perform this maintenance action now.
	This maintenance action should be performed on the next major maintenance day.
	No action is currently required.
	This maintenance action is selected.

Preparing the maintenance actions

The maintenance actions are sorted according to the date by when they should be performed. Use these dates for planning the maintenance actions, for example for ordering the required materials.

Performing the maintenance action

2 Select the maintenance action you want to perform.

The selected line turns blue.

3 Press .

The first screen of the wizard for performing the selected maintenance action is displayed. Usually, this is the maintenance description screen.

Press if you want to print the instructions before you start.

4 Follow the instructions on the screen.

A message will inform you when the maintenance action is complete. In addition, with maintenance actions that take some time, an acoustic signal is sounded. This allows you to do work away from the instrument while the maintenance action is in progress.

For information on how to perform individual maintenance actions, see *Maintenance actions* on page C-8.

■

WARNING

Incorrect results or processing stop due to incomplete maintenance actions

You can cancel a maintenance action any time by pressing ⊗.

If you interrupt the performing of a maintenance action that was due, its status will remain due, and you need to fully re-perform the action later.

If at all possible, complete a maintenance action without interrupting it.

Maintenance actions and their intervals

The following table lists the maintenance actions and shows how frequently they need to be performed.

Every effort has been made to ensure that all the information contained in this table is correct at the time of publication. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.

Maintenance actions with no defined interval need to be performed in particular situations, for example during troubleshooting.

Interval	Maintenance action
None	**Prime Fluid System**
None	**Abs. Air/Water Calibration**
None	**Clean Rotor And Heating Channel**
None	**Cleanup Database**
Daily	**Deproteinize Probe**
Weekly	**Clean Probe Manually**
Monthly	**Clean Reagent Disk**
Three-monthly	**Clean Water and Waste**
Three-monthly	**Replace Water Inlet Filter**
Six-monthly	**Clean Housing**
Six-monthly	**Replace Photometer Lamp**
Yearly	**Call Service Rep.**
Yearly	**Initialize Degasser Fluid Sensor**

Table C-1 Periodicity of maintenance actions

Maintenance actions

The following sections describe the maintenance actions of the main instrument.

For ISE-specific maintenance actions, see *ISE maintenance actions* on page E-42.

Safety information

WARNING

Injury through working solutions

Direct contact with cleaning solutions or other working solutions may cause personal injury. When handling such solutions, exercise the precautions required for handling them, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics cleaning solutions.

Personal injury or damage to the analyzer due to contact with instrument mechanism

Do not touch moving parts during instrument operation.

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Incorrect results due to build-up of contaminants

During use, contaminants may adhere to the probe. As a result, traces of analytes or reagents may be carried over to the next. Make sure to perform the probe maintenance actions as soon as they are due in order to prevent potentially false results.

Incorrect results or damage to the analyzer due to dust and soiling

The user can leave the main cover open while the system is in **Standby** status or while the instrument is shut down. This can cause dust and dirt being collected in the heating channel, which in turn might decrease the quality of the cuvettes.

Keep all covers closed. Open them only to perform operation actions.

Incorrect results or processing stop due to skipping maintenance actions

Not performing maintenance actions that are due may lead to situations where the system cannot continue processing orders, or it may lead to incorrect results. If at all possible, perform the maintenance actions when they are due.

WARNING

Incorrect results or damage to the analyzer due to wrong operation

Operators are required to have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Start all maintenance actions on the screen. Do not perform maintenance actions without the assistance of the user interface.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to a trained service representative.
- Follow standard laboratory practices, especially when working with biohazard material.

Incorrect results or processing stop due to incomplete maintenance actions

You can cancel a maintenance action any time by pressing ⊗.

If you interrupt the performing of a maintenance action that was due, its status will remain due, and you need to fully re-perform the action later.

If at all possible, complete a maintenance action without interrupting it.

Danger of poor measurement quality due to inadequate water quality

Inadequate water quality may lead to incorrect results. Always use purified water of the quality specified in section *Technical specifications*.

Infection by waste solution

Contact with waste solution may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Whenever the term "purified water" is used in this document, water of at least the quality specified in chapter *Technical specifications* must be used.

Deproteinize the probe

➔ **Utilities** > **Maintenance** > **Deproteinize Probe**

To maintain the efficiency of the instrument, you must clean and deproteinize the probe regularly to prevent the build-up of contaminants.

Operator time Approximately 5 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required
- ☐ ISE Deproteinizer
- ☐ Activator

Make sure that you have read and understood section *Safety information* on page C-8.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page C-8.
- *Incorrect results due to build-up of contaminants* on page C-8.

► To deproteinize the probe

1. Prepare one tube with ISE Deproteinizer and one with Activator.
2. Select the maintenance action **Deproteinize Probe**.
3. Press ⓞ.

   The maintenance definition screen is displayed.
4. Press ⓥ.

   A placement list is displayed.
5. Place the ISE Deproteinizer and Activator on the positions indicated on the screen.
6. Press ⓥ to confirm the placing.

   The system first deproteinizes and then activates the probe.

   A message will inform you when the maintenance action is complete.
7. Remove the tubes.
8. Press ⓧ.

■

Prime the fluid system

➔ **Utilities** > **Maintenance** > **Prime Fluid System**

Priming flushes the fluid system with water to ensure the paths in the fluid system (including pipette, tubing, and probe) are filled with fluid and are free of air bubbles. If air bubbles are present in the fluid system, your test results will be inaccurate.

Operator time Approximately 2 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required ☐ Purified water.

► To prime the fluid system

1. Check the external water and waste containers. If required, refill the water and empty the waste container.
2. Select the maintenance action **Prime Fluid System**.
3. Press ⓞ.

   The maintenance definition screen is displayed.
4. Press ⓥ.

   The system performs the priming actions automatically.

   A message will inform you when the maintenance action is complete.
5. Press ⓧ.

■

Clean the probe manually

➔ **Utilities > Maintenance > Clean Probe Manually**

You must clean the probe regularly by hand to prevent any build up of deposits that may affect results.

Operator time Approximately 1 minute.

Prerequisites The system must be in **Standby** status.

Tools and materials required
- ☐ 70% ethyl alcohol
- ☐ Tissues

Make sure that you have read and understood section *Safety information* on page C-8.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page C-8.
- *Incorrect results due to build-up of contaminants* on page C-8.
- *Infection by biohazardous materials* on page C-8.

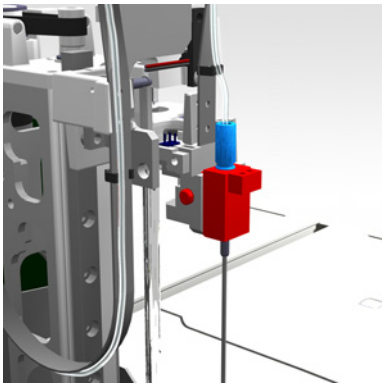
► To clean the probe

1. Select the maintenance action **Clean Probe Manually**.
2. Press ⓞ.

   The maintenance definition screen is displayed.
3. Press ⓥ.

   The system deactivates the transfer motors.
4. Remove the transfer head cover.

   Press the release buttons on both sides and lift.
5. Remove the probe with its holder.
   - Remove the tube from at least the first two tubing clips.
   - Press the release button on the side of the probe holder carriage and lift the probe holder with the probe. Be careful not to pull the tubing.



6 Hold the assembly by the probe holder and clean the probe using a tissue moistened with 70% ethyl alcohol.

Wipe from top to bottom several times.

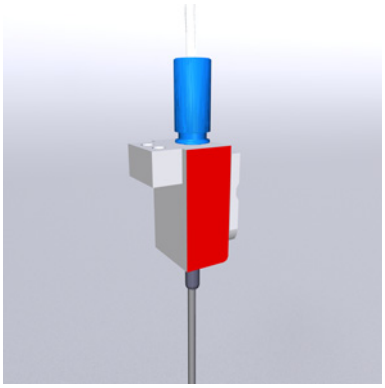
NOTICE

Probe damage and instrument malfunction due to inappropriate probe handling

Applying unilateral side pressure on the probe can lead to its deformation and consequently to instrument malfunction.

Make sure to apply equal pressure on both sides and to move exactly in the direction of the probe when wiping it.

7 Wipe the side of the probe holder that faces the level detection contact. Use a tissue moistened with 70% ethyl alcohol.



8 Reinstall the probe holder with the probe.

Press the release button on the side of the probe holder carriage before you insert the probe holder. Release the button when the holder is inserted.

Push down firmly until the release button latches on.

9 Fix the tube to the tubing clips.

10 Reinstall the transfer head cover.

Press down until the release buttons latch on.

11 Press ⊘.

The system automatically initializes the transfer head and performs the **Prime Fluid System** maintenance action.

A message will inform you when the maintenance action is complete.

12 Press ⊗.

■

Clean reagent disk and sample area

➔ **Utilities** > **Maintenance** > **Clean Reagent Disk**

To remove possible spillages you must clean the reagent disk and sample area regularly.

This maintenance action involves the following steps:

- Cleaning the reagent disk
- Cleaning the sample area

Operator time Approximately 10 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required

- ☐ Alcoholic cleansing tissues
- ☐ Tissues
- ☐ Commercial nonabrasive detergent

Make sure that you have read and understood section *Safety information* on page C-8.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page C-8.
- *Infection by biohazardous materials* on page C-8.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page C-8.

► To clean the reagent disk

1 Select the maintenance action **Clean Reagent Disk**.

2 Press .

The maintenance definition screen is displayed.

3 Press .

4 Open the main cover.

5 Remove the reagent disk.

6 Remove spillages and stains on the disk with alcoholic cleansing tissues.

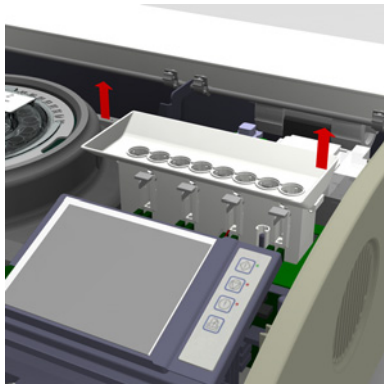
7 Wipe the inside of the reagent cooler with a cloth dampened with soapy water.

8 Reinsert the reagent disk.

For information on inserting the reagent disk, see *Preparing the reagent disk* on page B-21.

9 Open the right service flap.

10 Lift the sample tray from its fixture.



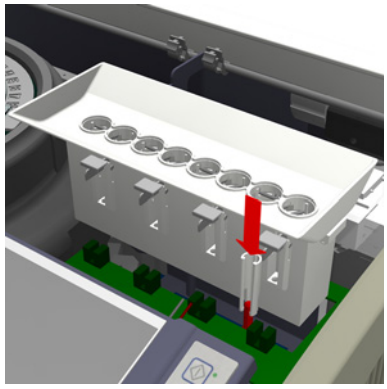
11 Wash the sample tray using detergent. (You can wash the tray in a dish washer.)

Do not disassemble the sample tray.

12 Leave the sample tray to dry or dry it using tissues.

13 Reinsert the sample tray.

Make sure to align the guides with the pins.



Press down firmly.

14 Close the right service flap and the main cover.

15 Press ⊘ to confirm that you have performed the maintenance action.

The system initializes automatically.

A message will inform you when the maintenance action is complete.

16 Press ⊗.

■

Clean the water and waste containers

➔ **Utilities > Maintenance > Clean Water and Waste**

You must clean the external water and fluid waste containers to prevent the build-up of contaminants, which can affect the water quality and therefore the quality of the results produced.

This maintenance action consists of the following steps:

- Cleaning the water container
- Cleaning the waste container

The water and waste containers are placed on the rack next to the **cobas c**111 instrument.

Operator time Approximately 10 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required

- ☐ Spare waste container
- ☐ Purified water
- ☐ Hypochlorite solution (0.6%)
- ☐ Alcoholic cleansing issues

Make sure that you have read and understood section *Safety information* on page C-8.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page C-8.
- *Infection by waste solution* on page C-9.
- *Infection by biohazardous materials* on page C-8.

► To clean the water container

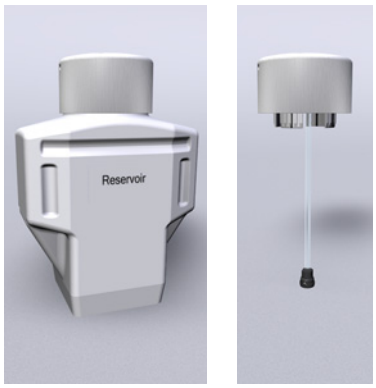
1 Select the maintenance action **Clean Water and Waste**.

2 Press ⏵.

The maintenance definition screen is displayed.

3 Press ✓.

4 Lift the tubing adapter from the white water container.



5 Place the tubing adapter on a clean surface.

6 Dispose of any remaining water.

7 Pour 500 mL hypochlorite solution in the water container.

8 Clean the water container with a brush.

9 Dispose of the solution.

10 Clean the interior of the water container manually using tissues. Remove any residue.

11 Rinse the water container with tap water at least four times.

12 Rinse the water container with purified water.

13 Wipe the suction pipe with a tissue.

14 Fill the water container with purified water.

15 Reinsert the tubing adapter into the water container. Press down firmly.

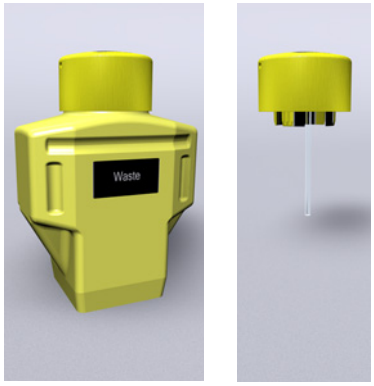
■

► To clean the waste container

1 Have the spare waste container ready.

The system periodically performs wash actions. Therefore, an external waste container must be connected at all times.

2 Remove the tubing adapter from the yellow waste container and insert it in the spare container.



3 Remove the bottle from the rack and place it on a firm and even surface.

4 Place the spare container on the rack.

5 Check that the tubing adapter is properly inserted.

6 Empty the removed waste container. Treat the fluid as biohazardous waste.

7 Pour 500 mL hypochlorite solution in the waste container.

8 Clean the container with a brush.

9 Dispose of the fluid. Treat it as biohazardous waste.

10 Clean the interior of the waste container manually using tissues. Remove any residue.

11 Rinse the waste container with tap water.

12 Empty the container completely.

13 Wipe the waste inlet with a tissue.

14 Reinsert the tubing adapter into the waste container. Press down firmly.

15 Press ✓.

The maintenance action **Prime Fluid System** is automatically performed.

A message will inform you when the maintenance action is complete.

16 Press ⊗.

■

Replace water inlet filter

➔ **Utilities > Maintenance > Replace Water Inlet Filter**

The water inlet filter in the external water container removes particulate matter from the water supply. You must replace this filter according to the maintenance action schedule.

The water container is placed on the rack next to the **cobas c** 111 instrument.

Operator time Approximately 10 minutes.

Prerequisites None

Tools and materials required

- ☐ Purified water
- ☐ Hypochlorite solution (0.6%)
- ☐ Tissues
- ☐ Water inlet filter

Make sure that you have read and understood section *Safety information* on page C-8.

The following warning messages in particular are relevant:

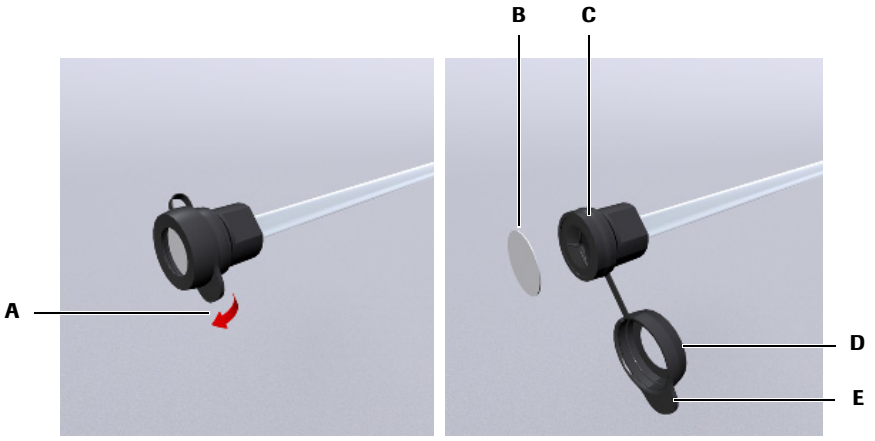
- *Injury through working solutions* on page C-8.

► To replace the water inlet filter

1. Select the maintenance action **Replace Water Inlet Filter**.
2. Press ⏵.

   The maintenance definition screen is displayed.
3. Press ✓.
4. Remove the tubing adapter from the water container.
5. Place the tubing adapter on a clean surface.

6 Replace the water inlet filter.



A Removing the retaining ring
B Filter
C Filter casing
D Retaining ring
E Tab on retaining ring

Figure C-2

- Remove the retaining ring by pulling it by its tab away from the filter casing (A, D, E).
- Remove the filter (B) and replace it with a new one.
- Place the retaining ring.

  Press it firmly on the filter casing by placing your thumb across it an applying equal pressure all around.

7 Reinsert the tubing adapter into the water container. Press down firmly.

8 Press ⊘.

The maintenance action **Prime Fluid System** is automatically performed.

A message will inform you when the maintenance action is complete.

9 Press ⊗.

■

Clean and disinfect housing

➔ **Utilities > Maintenance > Clean Housing**

You must clean the housing regularly to ensure that contaminants do not build up and affect the efficiency of the instrument as a measuring system.

Operator time Approximately 10 minutes.

Prerequisites Instrument is switched off.

Tools and materials required
- ☐ Ethyl alcohol
- ☐ Tissues

Make sure that you have read and understood section *Safety information* on page C-8.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page C-8.
- *Infection by biohazardous materials* on page C-8.

- To find out what steps are required, you can choose **Utilities** > **Maintenance** > **Clean Housing** and then press ⓞ. (The maintenance definition screen is displayed.)
- Do not press ⓞ at this stage. You do this only when you have completed the maintenance action. Instead, press ⊗ to close the screen.

► To clean the housing

1 Make sure the system is in **Standby** status.

2 Switch off the system.

3 Wipe all the outside of the instrument with alcoholic cleansing tissues.

4 Open the main cover and the right service flap.

5 Wipe all the inside of the cover and flap with alcoholic cleansing tissues.

6 Close the right service flap and then the main cover.

7 Push the transfer head to the rightmost position.

8 Open the main cover and the left service flap.

9 Wipe all the inside of the flap with alcoholic cleansing tissues.

10 Close the left service flap and the main cover.

11 Push the transfer head to its home position.

12 Remove the transfer head cover.

(Press the release buttons on both sides and lift.)

13 Wipe all the inside of the cover with alcoholic cleansing tissues.

14 Reinstall the transfer head cover.

(Push down until the release buttons latch on.)

15 Remove the left and right side panels.

16 Wipe the panels with alcoholic cleansing tissues.

17 Reinstall the left and right side panels.

18 Switch on the system.

The system performs internal checks and routines.

The startup phase may take a few minutes.

When the instrument is ready for use, the **Overview** tab is displayed, and its status is **Standby**.

19 Log on the system.

20 Choose **Utilities** > **Maintenance** > **Clean Housing**.

21 Press ⊙.

The maintenance definition screen is displayed.

22 Press ⊘.

A detailed maintenance definition screen is displayed.

23 Press ⊘ to confirm the completion of the maintenance action.

■

Clean up the database

➔ **Utilities** > **Maintenance** > **Cleanup Database**

This maintenance action restores the database to the condition where the instrument can work at its optimum. You typically use this action when you think that the instrument suddenly works slow, for example when displaying information on the screen takes long or when it takes long until an action starts after you have initiated it.

Operator time Approximately 10 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required None

► To clean up the database

1. Select the maintenance action **Cleanup Database**.
2. Press ⓞ.

   The maintenance definition screen is displayed.
3. Press ⓥ.

   An instructions screen is displayed while the database cleanup is performed.
4. When the maintenance action is complete, press ⓥ to confirm the completion.

■

Replace photometer lamp

➔ **Utilities > Maintenance > Replace Photometer Lamp**

It is essential that the photometer lamp maintains a constant intensity in successive absorbance measurements. After a certain time of use, the intensity of the light emitted by the lamp deteriorates, and the accuracy of the measurements may no longer meet the required standards. Therefore, the lamp must be periodically replaced. The system alerts you when the lamp should be replaced by changing the maintenance action status to due (entry turns red).

Operator time Approximately 20 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required

- ☐ Paper tissue
- ☐ Photometer lamp assembly (Lamp, socket and cable are pre-assembled.)
- ☐ Cuvette segments
- ☐ Clean cloth

Make sure that you have read and understood section *Safety information* on page C-8.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page C-8.
- *Infection by biohazardous materials* on page C-8.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page C-8.

► To replace the photometer lamp

1 Select the maintenance action **Replace Photometer Lamp**.

2 Press ⏵.

The maintenance definition screen is displayed.

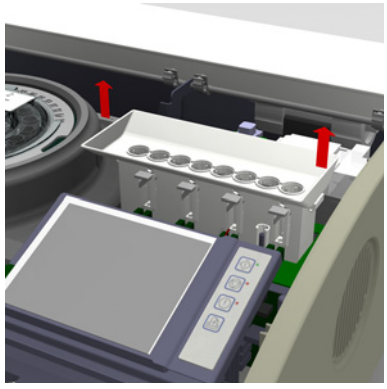
3 Press ✓.

The system switches off the lamp, and the transfer head moves to the home position.

Preparing the instrument

4 Open the main cover and the right service flap.

5 Remove the sample tray by lifting it.



CAUTION

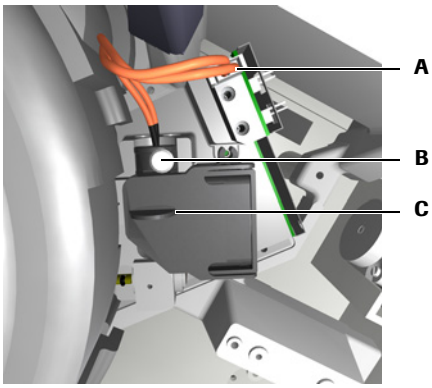
Injury through hot parts

Direct contact with hot parts may result in injury.

Do not touch the lamp assembly with bare hands. Let the lamp cool down for about ten minutes before touching any part of the lamp housing.

Removing the lamp

6 Unplug the power connector (A).



A Power connector
B Assembly screw
C Cover

Figure C-3

7 Lift the photometer lamp housing cover (C).

8 Unscrew (B) the lamp assembly and remove it.

Installing the new lamp

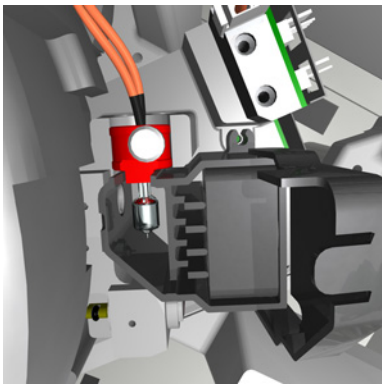
9 Insert the new lamp assembly.

WARNING

Incorrect results through soiled lamp

Touching the lamp with bare fingers reduces the life of the bulb and may affect the consistency of measurements made with the absorbance photometer.

Hold the lamp assembly by its screw.



Hold the assembly by the screw and fit the lamp socket in the guides.

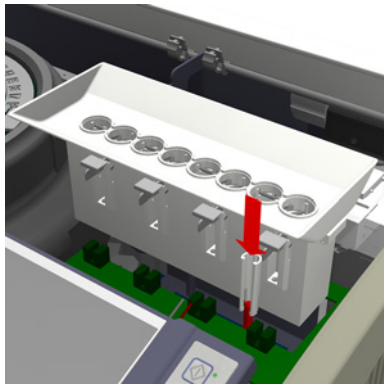
10 Fasten the screw of the lamp assembly.

11 Close the photometer lamp housing cover.

12 Plug the power connector into its socket.

Preparing the instrument

13 Reinsert the sample tray.



14 Close the right service flap and the main cover.

15 Press ⓥ.

The system automatically initializes the instrument.

A message will inform you when the maintenance action is complete.

16 Press ⓧ.

17 Perform an air/water calibration.

You cannot process orders unless you perform this action.

See *Perform an air/water calibration* on page C-28.

■

Contact service representative

➔ **Utilities** > **Maintenance** > **Call Service Rep.**

To ensure smooth operation of the instrument, a service representative periodically needs to perform some preventive maintenance tasks.

The system displays a message when this maintenance action is due.

Operator time Approximately 2 minutes.

(A service representative takes about 3 hours to perform preventive maintenance for a system without an ISE unit, 4 hours including the ISE unit.)

Prerequisites None

► To initiate preventive maintenance

1. A message screen reminds you that you should contact your service representative.
2. Select the maintenance action **Call Service Rep.**
3. Press ⓞ.

   The maintenance definition screen is displayed.
4. Press ⓥ.

   An instructions screen is displayed.
5. Contact your service representative to arrange for preventive maintenance.
6. Press ⓥ.

■

Perform an air/water calibration

➔ **Utilities > Maintenance > Abs. Air/Water Calibration**

The absorbance photometer calibration determines the air/water correction values that are needed for result calculation. In addition, the obtained absorbance values for an empty cuvette at each wavelength are used as a reference for the cuvette blank check.

Operator time Approximately 5 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required ☐ 2 cuvette segments with empty cuvettes

Make sure that you have read and understood section *Safety information* on page C-8.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page C-8.
- *Infection by biohazardous materials* on page C-8.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page C-8.

► To perform an air/water calibration

1. Choose **Utilities** > **Maintenance** > **Abs. Air/Water Calibration**.
2. Press ⓞ.

   Your are asked to insert a cuvette segment with empty cuvettes.
3. Open the main cover.
4. If there is a segment in the cuvette ring remove it and check whether there are used cuvettes.

   If all cuvettes of this segment are empty, you can reinsert it.
5. Place a cuvette segment with empty cuvettes on the cuvette ring.
6. Press ⓥ.

   Your are asked to insert a second cuvette segment with empty cuvettes.
7. If there is a segment on in the cuvette ring remove it and check whether there are used cuvettes.

   If all cuvettes of this segment are empty, you can reinsert it.
8. Place the cuvette segment with empty cuvettes on the cuvette ring.
9. Close the main cover.
10. Press ⓥ.

    The system performs the calibration measurements. (It first measures all cuvettes empty, pipettes water in the cuvettes, and measures them again.)

    A message will inform you when the measurements are complete.
11. Scroll to display the results, if required.
12. Check the **Outlier statistics**.

13 Press ⊘ to accept the results.

If at this stage, you press ⊗, the results are not stored and the maintenance action is deemed not performed.

14 Remove the used cuvettes or replace them with empty ones.

■

Initialize degasser fluid sensor

➔ **Utilities > Maintenance > Initialize Degasser Fluid Sensor**

The degasser fluid sensor checks whether there is air in the water supply to the syringe assembly. Air in the water supply may lead to inaccurate pipetting and ultimately to incorrect results. Therefore, the sensor needs to be initialized to ensure its proper functioning.

Operator time Approximately 5 minutes.

Prerequisites The system must be in **Standby** status.

All covers must be closed.

Tools and materials required
- ☐ Full external water container
- ☐ Clean cloth

► To initialize the degasser fluid sensor

1 Make sure that all covers on the instrument are closed.

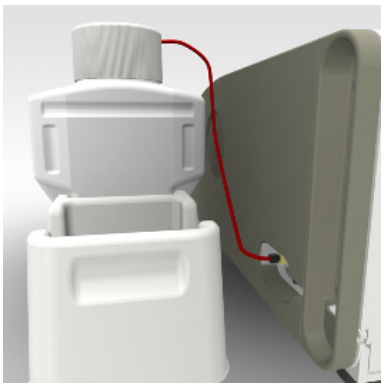
2 Choose **Utilities** > **Maintenance** > **Initialize Degasser Fluid Sensor**.

An instructions screen is displayed.

3 Press ✓.

The maintenance definition screen is displayed.

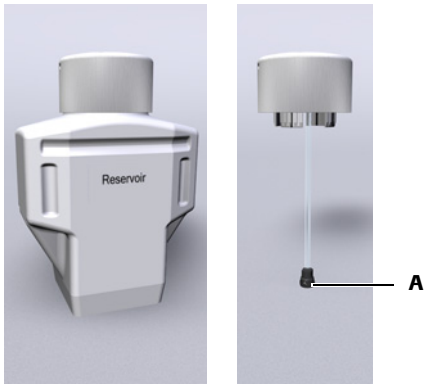
4 Check whether the tube connecting the external water container with the instrument is full of water or contains air bubbles.



5 Do one of the following:

If	Do this
You cannot see any air bubbles	1. Continue with step 6.
You can see air bubbles or the tube is empty	1. Press ⊗ to abort this maintenance action. 2. Perform the maintenance action **Prime Fluid System**. 3. Restart the maintenance action **Initialize Degasser Fluid Sensor**.

6 Lift the tubing adapter from the white water container.



7 Place the tubing adapter on a clean surface.

Make sure the filter (A) is not obstructed and air can get to it.

8 Press ⓥ to initialize the fluid sensor.

The system aspirates air through the tubing adapter and initializes the fluid sensor.

When initialization is complete, you will be asked to insert the tubing adapter.

9 Insert the tubing adapter in the water container.

10 Press ⓥ.

The fluid system is primed.

A message will inform you when the maintenance action is complete.

11 Press ⓧ.

■

Clean rotor and heating channel

Perform this maintenance action whenever a message asks you to do so.

Operator time Approximately 15 minutes.

Tools and materials required
- ☐ 95% ethyl alcohol
- ☐ Lint free tissues

Make sure that you have read and understood section *Safety information* on page C-8.
The following warning messages in particular are relevant:
- *Injury through working solutions* on page C-8.
- *Infection by biohazardous materials* on page C-8.

► To clean the rotor and heating channel

1 Remove the reagent disk.
- Choose **Overview** > > .

  A screen is displayed, asking you to remove the reagent disk.
- Open the main cover.
- Remove the reagent disk.
- Close the main cover.

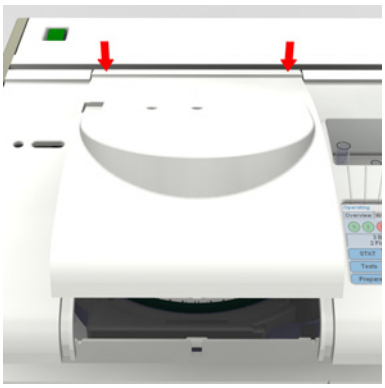
2 Remove all cuvettes.
- Choose **Overview** > .
- Open the main cover.
- Press a segment button.
- Remove the segment.
- Press to confirm the removal.

  Remove all segments as described above.
- Close the main cover.

3 Switch off the instrument.

4 Move the transfer head to the sample area.

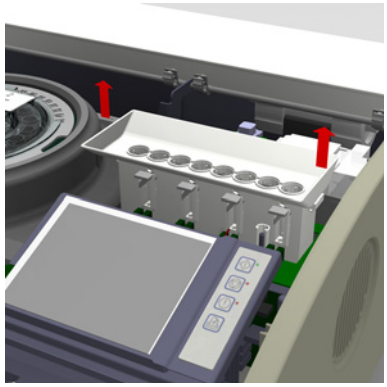
5 Open and remove the main cover and left service flap.



6 Move the transfer head to its leftmost position.

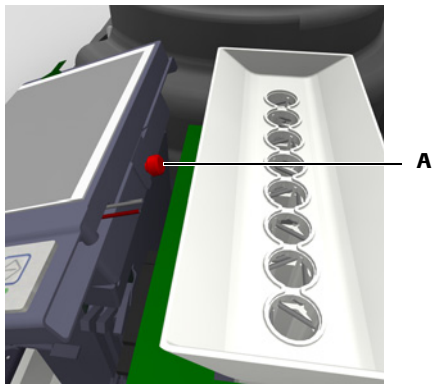
7 Open and remove the right service flap.

8 Remove the sample tray.



Removing the rotor

9 Loosen the display fixation screw (A).

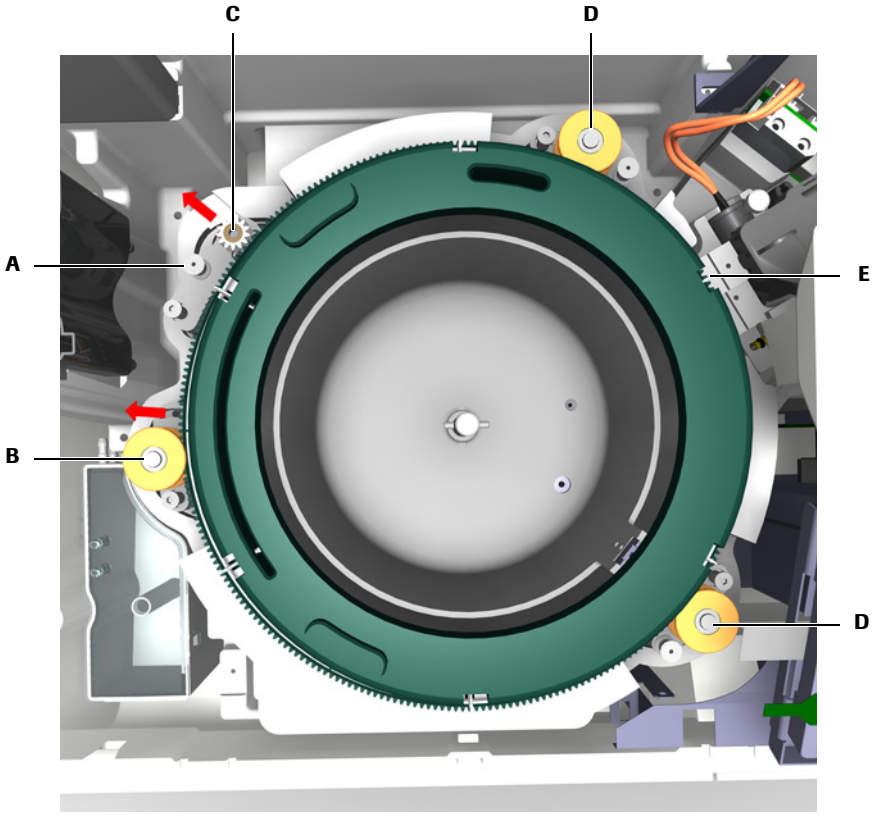


10 Tilt forward the display.

11 Move transfer head to its rightmost position.

12 Remove the upper rotor shell.

13 For each of the two rotor bearings to the right, loosen slightly one of the fixation screws and completely unscrew the other. (Use a screw driver to loosen the screws, if required.) Then pull away from the rotor the side of the bearing that you completely unscrewed.



A Retention pin of motor
B Spring-loaded rotor bearing
C Rotor motor
D Fixed rotor bearings
E Photometer lens (not shown)

Figure C-4

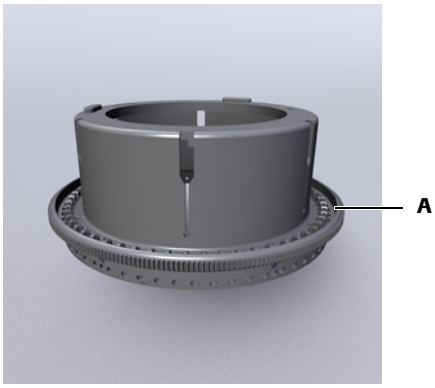
14 From the rotor motor, slightly lift the retention pin, move the motor away from the rotor and engage the pin to fix the motor in the removed position.

Make sure to use the hole nearer to the front of the instrument for arresting the bearing with the pin.

15 With one hand, release the spring-loaded bearing from the rotor, and with the other hand lift the rotor.

Cleaning the rotor

16 Rinse the cuvette ring (A) under running water.



NOTICE

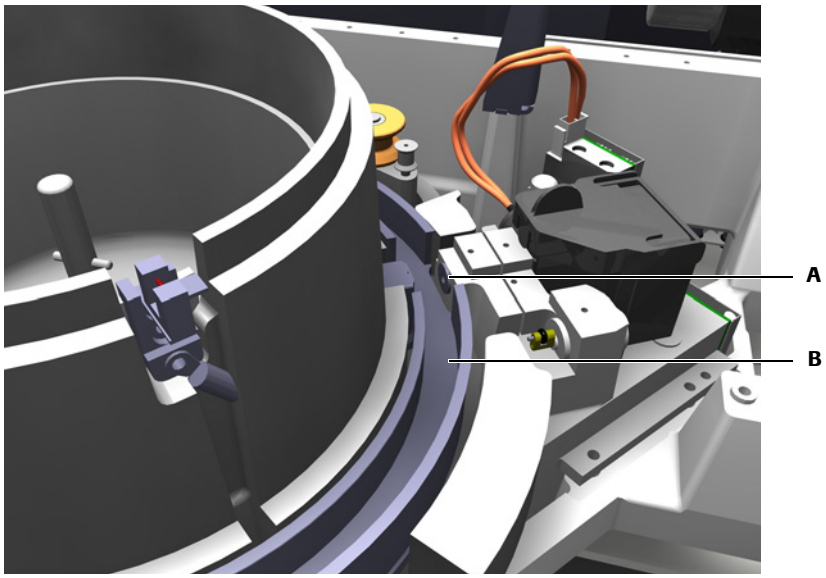
Do not use any cloth to clean or dry the rotor. This could leave dust and lint on the Abs. inspection holes and so prevent proper measurement.

17 Leave the rotor to dry.

Cleaning the heating channel

18 Clean the heating channel (B) with a lint free tissue or a cloth moistened with ethyl alcohol.

Make sure not to touch the photometer lens (A).



Reinstallation

19 With one hand, pull the spring-loaded bearing away from the rotor position, and with the other hand insert the rotor.

20 Engage the right rotor bearings and fasten the fixation screws.

21 Move the rotor to test its smooth running.

22 Hold the spring-loaded rotor motor in position, lift the retention pin and release the motor gently.

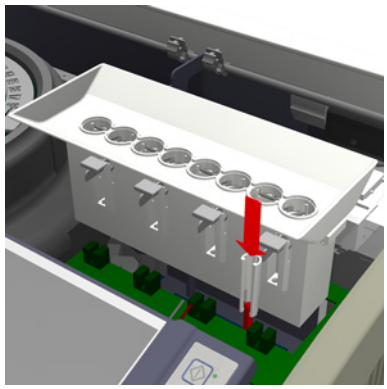
23 Move the transfer head to its leftmost position.

24 Fit the upper rotor shell.

25 Fold down the display and fasten the fixation screw.

26 Install the sample tray.

Make sure to align the guides with the pins.



Press down firmly.

27 Install and close the right service flap.

28 Move the transfer head to its rightmost position.

29 Install and close the left service flap and main cover.

Finishing the maintenance action

30 Switch on the instrument.

31 Wait for initialization to finish.

32 Log on to the system.

33 Insert the reagent disk.

See *Preparing the reagent disk* on page B-21

■

Troubleshooting D

9 Messages and alarms D-3
10 Result flags D-23
11 Troubleshooting D-39

Messages and alarms

How to make the most of the available information

In this chapter, you will find information on messages generated by the **cobas c** 111 instrument, and on how to use them and react to them.

In this chapter *Chapter* **9**

About messages D-5
Message screen D-5
Acoustic signals D-6
Alarm monitor D-6
Reacting to alarm messages D-7
Printing alarm messages D-8
Confirming alarm messages D-9
Exporting the alarm message log D-9
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About messages

The system performs numerous checks. When a certain event has occurred or when an irregularity is detected, a message is generated. Messages are displayed in two ways:

- Immediate feedback on user actions is displayed in a *pop-up message screen*.
- Information concerning a problem that occurred during operation is reported as *alarm messages* in the *alarm monitor*.

Alarm messages are stored in a log file, which you can export.

See *Exporting the alarm message log* on page D-9.

Message screen

Message screens are displayed automatically as soon as the message is generated.

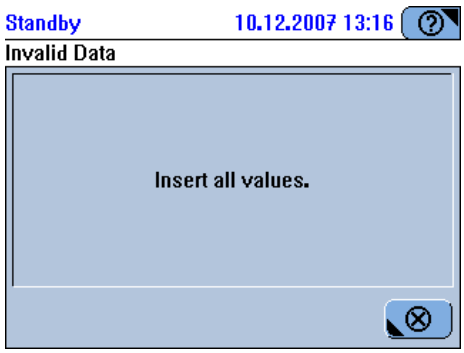


Figure D-1 Message screen

Read the message and press ⊗ to close the screen.

Acoustic signals

The operator is alerted to certain events by an acoustic signal.

The following events trigger an acoustic signal.

- An alarm was generated.
- The Main cover is open while the system is in **Operating** status.
- A run is finished. (The system status has changed from **Operating** to **Standby**.)
- A maintenance action is complete (provided it is a longer maintenance action where no user intervention is required).

You can adjust the volume of all generated acoustic signals (**Utilities** > **Configuration** > **System** > **Volume**).

You can also turn on and off acoustic signals:

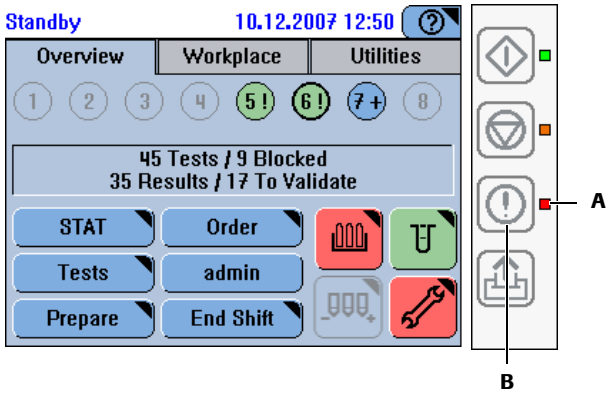
- Choose **Utilities** > **Configuration** > **System** > **Sound Effects** to turn on and off the acoustic signals other than alarm and warning signals.
- Choose **Utilities** > **Configuration** > **System** > **Volume** and set the value to zero to turn off all acoustic signals.

System on page B-168.

Alarm monitor

Messages concerning an irregularity that occurred during operation can be viewed in the alarm monitor. The alarm LED alerts you when such messages are generated.

Alarm button and LED



A Alarm LED **B** Alarm button

Figure D-2 Alarm LED

The alarm button is always active, even if you are not logged on the system.

Reacting to alarm messages

► To react to an alarm message

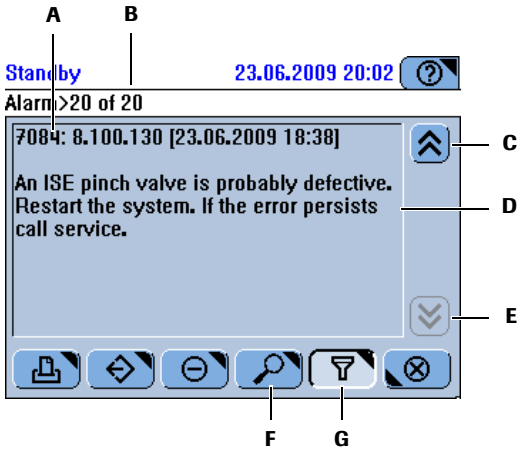
1 Observe the alarm LED.

No color Off	There are no unconfirmed alarm messages.
Yellow	There is at least one unconfirmed alarm message. You need to deal with it as soon as possible.
Red	There is at least one unconfirmed alarm message. You need to deal with it immediately, processing may not be able to continue unless you do so.

An acoustic signal is sounded when an alarm is generated. You can adjust the volume (**Utilities** > **Configuration** > **System** > **Volume**).

2 Press the **Alarm** button.

The most recently generated alarm message in this list is displayed. Which messages are included in this list depends on the filter criteria that are applied to it.



A Alarm ID
B Total number of messages in the list.
C Display the previous alarm message.
D Problem description and short remedy suggestion
E Display the next alarm message.
F Display additional information.
G Display the filter options for the alarm list.

Figure D-3

The alarm list can contain up to 250 messages. When this number is reached, the oldest message is automatically deleted when a new one is generated.

3 To limit the number of messages that are contained in the list, press .

A list of filter options is displayed.

- Select **Not confirmed** to include in the list all alarm messages that have not yet been confirmed by the user.
- Select **Today's alarms** to include in the list all alarm messages that so far have been generated on the current day.
- Select **Complete list** to include in the list all alarm messages that are stored in the alarm database.

4 Select the message you are interested in. Use ⏫ and ⏬ to display the previous and next message respectively.

5 Do one of the following:

- Press 🔎 to display more detailed information.

  (If this button is not available there is no additional information.)
- Press 🖶 to print alarm messages.
- Press 📤 to export the log file.

  👁 See *Exporting the alarm message log* on page D-9.

6 When you have dealt with the issue, press ⊖ to confirm that you have dealt with the issue. The message is deleted from the **Not confirmed** list but it remains in the other lists and the alarm messages log, which you can export.

👁 See *Confirming alarm messages* on page D-9.

■

Printing alarm messages

When you print alarm messages, their details are included in the printout.

► To print alarm messages

1 Press ⓘ.

2 Press 🖶.

A screen is displayed for defining which alarm messages should be printed.

3 Do one of the following:

- Press **All** to print all messages that have not been dealt with.
- Press **Selected** to print the current message.

■

Confirming alarm messages

Confirming a message means that you have dealt with the issue mentioned in it.

► To confirm a message

1 Press ⓘ.

2 Select the message. (Use ⌃ and ⌄ to display the previous and next message respectively.)

3 Press ⊖.

A confirmation dialog box is displayed.

- Press **All** to remove all messages from the list.
- Press **Selected** to remove the currently displayed message.

The message or messages are removed from the **Not confirmed** list, but they remain in the other lists and the alarm messages log, which you can export.

When all messages are confirmed the Alarm LED is turned off (not lit).

■

Exporting the alarm message log

► To export the message log file

1 Press ⓘ.

2 Press ⇦.

A screen is displayed asking you to insert a USB stick.

3 Insert the USB stick.

4 Press ✓ to confirm the insertion.

A screen is displayed for selecting a directory.

Press ***.tgz** to display log files only.

Press ***.*** to display all files and directories.

5 Select a directory for the error log.

6 Press ✓ to confirm the selection.

All log files are added to a file with the name format log_yyyymmddhhmmss.tgz and copied to the stick. The error log file has the name format err_yyyymmddhhmmss.log.

■

List of alarm messages

In the following table, the variables %s and %d are used, they represent text and numbers.

ID	Message	Comment
0000	Unknown message, id=%d!	
0001	A fatal system exception software error (%d) occurred.	Restart the system. If the error recurs export the log files while the system stays in the error condition. If the error persists call service.
0002	An internal software error (%d) occurred while updating the configuration.	Restart the system. If the error recurs export the log files while the system stays in the error condition. If the error persists call service.
0003	A software error occurred. Order (%d, %d) could not be processed.	Delete the orders that are not processed yet. If the error recurs export the log files while the system stays in the error condition. If the error persists call service.
0004	A software error occurred. The unit is not ready, order (%d) rejected.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
0005	A mathematical exception arose.	Repeat the order. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
0006	Last calculation cycle (%d) too short.	Repeat the order. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
0007	Failed to calculate linear regression.	Repeat the order. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
0008	The cycle range (%d..%d) is not valid.	Repeat the order. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
0010	The reaction direction (%d) is invalid.	Repeat the order. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
0011	An internal communication error occurred. The received IPC message (%d, %d) could not be interpreted.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
0012	A software error occurred. The status of an order is invalid (%d.%d).	Delete and redefine the order. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
0017	The installed language version is out of date (%s, %s).	Install the language version that belongs to the currently installed system software version. If the error persists call service.
0018	The current system date and time are invalid.	Correct the date and time settings in Configuration. If the error persists call service.
5001	Air detected in the fluid system. Water container or cleaner bottle is empty.	

Table D-1 List of alarm messages

ID	Message	Comment
5002	[%d] Air detected in the fluid system.	Refill the water container. Check the filling level of the cleaner bottle. Replace the cleaner bottle if required. Perform <Prime Fluid System>. If the error persists call service.
5003	[%s] An internal software error occurred. A parameter is not valid.	Restart the system. If the error persists call service.
5004	[%s] Error syringe motor. The syringe motor could not be started.	Restart the system. If the error persists call service.
5010	[%s] Initialization of syringe failed.	Switch off instrument. Remove right side panel. Check for syringe mechanism jamming or blockage. Ensure correct syringe installation. Restart the system. If the error persists call service.
5013	[%s] Error mixer motor. The mixer motor could not be started.	Restart the system. If the error persists call service.
5019	[%s] Initialization of the mixer motor failed.	Switch off the instrument. Remove the transfer head cover. Check if the mixing mechanism is jamming or blocked. Restart the system. If the error persists call service.
5022	[%s] Error temperature sensor analyzer heating system. The sensor does not react anymore.	Restart the system. If the error persists call service.
5024	[%s] Error temperature sensor analyzer cooling system. The sensor does not react anymore.	Restart the system. If the error persists call service.
5026	[%s] Error temperature sensor cooling system. The heat sink temperature sensor does not react anymore.	Restart the system. If the error persists call service.
5028	[%s] Error temperature sensor instrument. The ambient temperature sensor does not react anymore.	Restart the system. If the error persists call service.
5030	[%s] Error wash pump P1. The wash pump could not be started.	Restart the system. If the error persists call service.
5032	[%s] Error waste pump P2. The waste pump could not be started.	Restart the system. If the error persists call service.
5034	[%s] Error wash valve V1. The valve does not react anymore.	Restart the system. If the error persists call service.
5036	[%s] Error cleaner valve V2. The valve does not react anymore.	Restart the system. If the error persists call service.
5038	[%s] Error analyzer heating system. The heating system does not react anymore.	Restart the system. If the error persists call service.
5040	[%s] Error cooling system. One of the Peltier elements does not react anymore.	Restart the system. If the error persists call service.
5044	[%s] Error main board fan. The fan could not be started or the fan speed is not correct.	Restart the system. If the error persists call service.
5047	[%s] Error cooling fan. The fan could not be started.	Restart the system. If the error persists call service.
5049	[%s] Error sample area fan. Switch off the instrument.	Remove the right side panel and check if the fan is jamming or blocked. If possible eliminate the problem. Restart the system. If the error persists call service.
5052	[%s] Error cooling system. The cooling heat sink overheated.	Ensure unrestricted cooling air circulation. Check the cooling fan and make sure the external vent is not blocked. Restart the system. If the error persists call service.
5054	[%s] The analyzer heating system overheated.	Switch off the instrument and wait 15 minutes to let cool down the analyzer. Restart the system. If the error persists call service.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
5055	[%s] The analyzer temperature is outside the range.	Restart the system. If the error persists call service.
5056	[%s] The calibration of the transfer head fluid sensor failed.	Ensure that the sample probe tube is correctly installed. Ensure that the syringe is correctly installed. Restart the system. If the error persists call service.
5058	[%s] Error fluid sensor transfer head. The sensor does not react anymore.	Restart the system. If the problem persists, call service.
5060	[%s] A not specified hardware error (%d) was reported by the Multi-Slave control.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
5061	[%d] Air detected in the fluid system.	Refill the water container. Check the filling level of the cleaner bottle. Replace the cleaner bottle if required. Perform <Prime Fluid System>. If the error persists call service.
5062	The degasser fluid sensor is not initialized.	Perform <Initialize Degasser Fluid Sensor>. Follow the instructions provided on the display. If the error persists call service.
5063	[%s] Error sample area fan.	Switch off the instrument. Remove the right side panel and check if the fan is jamming or blocked. If possible eliminate the problem. Restart the system. If the error persists call service.
5064	[%s] Error fluid sensor degasser. The sensor does not react anymore.	Restart the system. If the error persists call service.
6001	[%s] Photometer error. Signal is invalid or unstable.	Switch off the instrument. Remove and clean the rotor. In case of a recurrence perform <Replace Photometer Lamp> and <Abs Air/Water Calibration>. If the error persists call service.
6002	[%s] Photometer error. The photometer has a wrong status because initialization has not been successfully performed yet.	Restart the system. If the error persists call service.
6018	[%s] A not specified photometer hardware error (%d) was reported by the photometer.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
6019	[%s] Photometer error. The photometer signals were outside the range while performing a photometer initialization or a photometer measurement.	Restart the system. If the error persists call service.
6020	[%s] Photometer lamp error.	Perform <Clean Rotor and Heating Channel>. If the error persists, replace the photometer lamp. Perform first the maintenance action <Replace Photometer Lamp> and then <Abs Air/Water Calibration>.
6021	[%s] Photometer error. The lamp voltage is outside the range.	Restart the system. If the error persists call service.
6022	[%s] Photometer error. The internal photometer 15 V power supply failed.	Restart the system. If the error persists call service.
6023	[%s] Photometer error. The lamp current is outside the range.	Perform first the maintenance action <Replace Photometer Lamp> and then <Abs Air/Water Calibration>. Restart the system. If the error persists call service.
6024	[%s] Photometer error. Either the lamp fan is not running or its speed is not correct.	Switch off the instrument. Open the main cover and check if the lamp fan is jamming or blocked. Restart the system. If the error persists call service.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
6025	[%s] Photometer error. Either the dark shutter motor does not work or the shutter mechanism is jamming or blocked.	Restart the system. If the error persists call service.
6026	[%s] Photometer error. A problem caused by the internal circuitry has been detected.	Restart the system. If the error persists call service.
6027	[%s] Photometer error. The photometer signals are outside the range while performing a dark measurement.	Restart the system. If the error persists call service.
6029	[%s] Photometer error. A problem caused by the internal circuitry has been detected.	Restart the system. If the error persists call service.
6030	[%s] Initialization of the rotor failed.	Switch off the instrument. Remove the rotor and clean all rotor measurement holes. Reinstall the rotor. Restart the system. If the error persists call service.
6031	[%s] Photometer error. The photometer dark signal is not stable.	Restart the system. If the error persists call service.
7001	[%d] An Instrument Control software exception error occurred.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7002	[%d] A software error occurred.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7004	[%d] An internal communication software error occurred.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7006	[%s] A not specified hardware error (%d) was reported.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7007	[%d] An internal communication error (%d) occurred. A control unit could not be connected.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7008	[%d] A software error occurred that was caused by an unexpected system situation.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7009	The LAN connection to the IC software failed.	Check the external Ethernet cable. Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7010	Instrument initialization failed.	Check for previous errors. Switch off instr. Check transfer mechanism. Restart system. If error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7011	Failed to aspirate sample from tube on position %d.	Ensure that there is enough sample present. For maintenance tasks ensure to provide enough Activator, ISE Deproteinizer and ISE Etcher. If the error persists call service.
7012	Failed to identify the reagent disk. This is probably a consequential error.	Check for previous errors and eliminate the cause. Remove the reagent disk and check the ID tabs. Reinsert the reagent disk correctly.
7013	[%s] Position error X-transfer. Switch off the instrument.	Check if the X-transfer is blocked or jamming. Eliminate the cause. Restart the system. If the error persists call service.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
7014	[%s] %s electrode is not stable during sample measurement.	Perform restart. Perform <Electrode Service>. Check ISE Ref solution tubing for obstructions. Replace electrode.
7015	[%s] %s electrode is not stable during calibrator measurement.	Perform restart. Perform <Electrode Service>. Check ISE Ref solution tubing for obstructions. Replace electrode.
7016	[%s] Initialization of the ISE unit failed due to a fluid transport problem.	Check the ISE tower and the ISE tubing for obstructions and leaks. Check the electrodes. Perform <Initialize ISE Unit>. If the error persists call service.
7017	[%s] The ISE sample sensor could not detect ISE Etcher.	Check the ISE tower and the ISE tubing for obstructions and leaks. Ensure that the tubing is correctly inserted into the sample sensor. If the error persists call service.
7018	[%d] The probe is not straight or not properly mounted.	Check that the probe is properly mounted. Perform <Replace Probe>.
7019	[%d] Transfer initialization failed due to a level detection problem.	Clean the transfer init plate. Ensure that the probe is not bent and installed correctly. Restart the system. If the error persists call service.
7020	[%d] Transfer initialization failed due to an open main cover.	Ensure that all covers are closed. Restart the system.
7021	[%d] Instrument failed to initialize due to dirty init plate or probe.	Perform <Clean Probe Manually> and restart the system. If the problem persists, call service.
7022	[%s] Motor %d movement impeded.	Perform restart. If the problem persists call service.
7033	[%s] Position error Z-transfer.	Switch off the instrument. Check if the Z-transfer is blocked or jamming. Eliminate the problem. Restart the system. If the error persists call service.
7034	[%s] Either a rotor or an X-transfer or a Z-transfer motion control error occurred.	Restart the system. If the error persists call service.
7036	[%s] The level detection frequency is outside the range.	Clean the probe and probe holder. Replace the water inlet filter. Ensure that the system water meets the specifications. Restart the system. If the error persists call service.
7037	[%s] The level detection frequency is outside the range.	Clean the probe and probe holder. Check the level detection cable for damage. Ensure that the cable is connected correctly. Restart the system. If the error persists call service.
7038	[%s] Motor %d error (overheated).	Switch off the instrument. Check for smooth transfer movements. Restart the system. If the problem persists call service.
7039	[%s] Power supply error. One or more internally used voltages are outside the range.	Switch off the instrument. Check the fuses F1 through F4 and replace blown fuses. Restart the system. If the error persists call service.
7042	[%s] Fuse F1 blown.	Switch off the instrument. Check fuse F1. If necessary replace fuse F1. Restart the system. If the error persists call service.
7043	[%s] Fuse F2 blown.	Switch off the instrument. Check fuse F2. If necessary replace fuse F2. Restart the system. If the error persists call service.
7044	[%s] Fuse F3 blown.	Switch off the instrument. Check fuse F3. If necessary replace fuse F3. Restart the system. If the error persists call service.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
7045	[%s] Fuse F4 blown.	Switch off the instrument. Check fuse F4. If necessary replace fuse F4. Restart the system. If the error persists call service.
7046	[%s] The initialization of the rotor failed.	Switch off the instrument. Check if the rotor is jamming or blocked. Clean the rotor initialization light barrier. Restart the system. If the error persists call service.
7051	[%s] Error rotor motor. The motor could not be started.	Restart the system. If the error persists call service.
7052	[%s] Error motor X-transfer. The motor could not be started.	Restart the system. If the error persists call service.
7053	[%s] Error motor Z-transfer. The motor could not be started.	Restart the system. If the error persists call service.
7057	[%s] The ISE sample sensor is not calibrated or no calibration data is available.	Perform <Initialize ISE Unit>. If the error persists call service.
7058	[%s] ISE sample sensor could not detect fluid.	Check the ISE tower and the ISE tubing for obstructions and leaks. Ensure that the electrodes are installed correctly. If the error persists call service.
7059	[%s] The ISE sample sensor could not detect the end of the transported fluid segment.	Check the ISE tower and the ISE tubing for obstructions and leaks. If the error persists call service.
7060	[%s] The calibration of the ISE sample sensor failed.	Check the filling level of the ISE Cal bottle. Check the ISE tubing for obstructions and leaks. Perform <Initialize ISE Unit>. If the error persists call service.
7061	[%s] The calibration of the ISE sample sensor failed.	Check the filling level of the ISE Cal bottle. Check the ISE tubing for obstructions and leaks. Perform <Initialize ISE Unit>. If the error persists call service.
7062	[%s] The ISE sample sensor could not detect calibrator.	Check the filling level of the ISE Cal bottle. Check the ISE tubing for obstructions and leaks. Perform <Initialize ISE Unit>. If the error persists call service.
7063	[%s] The ISE sample sensor could not detect the end of the calibrator segment.	Check the ISE tubing for obstructions and leaks. Perform <Initialize ISE Unit>. If the error persists call service.
7064	[%s] The ISE sample sensor could not detect Activator during initialization.	Check the ISE tower and ISE tubing for obstructions and leaks. Perform <Initialize ISE Unit>. If the error persists call service.
7065	[%s] Calibration of the ISE reference sensor failed, no valid calibration data are available.	Check the filling level of ISE Ref. Perform <Initialize ISE Reference Sensor>. If the error persists call service.
7066	An internal control unit (%d) reported a wrong firmware version.	Reinstall the system software.
7067	An internal control unit (%d) reported a checksum or an attach error.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7068	[%d] Wash aborted due to open cover.	Close the cover and restart the system.
7069	[%d] Transfer initialization failed due to an open main cover.	Ensure that all covers are closed. Restart the system.
7070	The probe crashed or the reagent bottle set %s became unexpectedly empty.	Check if the probe is obstructed. Check the filling level of the associated reagent bottle.
7071	Photometer error. Signal is invalid or unstable.	Switch off the instrument. Remove and clean the rotor. If the error recurs perform <Replace Photometer Lamp> and <Abs Air/Water Calibration>. If the error persists call service.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
7072	[%d] The reagent mixing failed due to a level detection problem.	Check if the probe is obstructed. Check the filling level of the associated reagent bottle. If the error persists call service.
7073	[%s] Peristaltic pump speed is outside the range.	Check ISE tubing for obstructions and leaks. Ensure that the electrode tension lever and the peristaltic pump cover are closed. Perform <Initialize ISE Unit>. If the error persists call service.
7074	[%s] The detected sample or calibrator segment is too short.	Check the ISE tubing for obstructions and leaks. Ensure that the electrodes are installed correctly. If the error persists call service.
7075	[%s] A timeout error occurred while performing an ISE measurement.	Restart the system and repeat the measurement. If the error persists call service.
7076	[%s] Initialization of the ISE unit failed due to a fluid transport problem.	Check the ISE tower and the ISE tubing for obstructions and leaks. Check the electrodes. Perform <Initialize ISE Unit>. If the error persists call service.
7083	[%s] The ISE bypass tubing is blocked.	Perform <Replace ISE Unit Tubing>. Follow the instructions in the Operator's Manual. If the error persists call service.
7084	[%s] An ISE pinch valve is probably defective.	Restart the system. If the error persists call service.
7086	[%s] The ISE air pressure is outside the range.	Check the air tubing underneath the ISE tower for obstructions. If the error persists call service.
7087	[%s] ISE air pressure sensor detected that the pressure is too low.	Restart the system. If the problem persists, call service.
7088	[%s] A failure of the internal ISE power supply has been detected.	Restart the system. If the error persists call service.
7099	[%s] Weight sensors of the ISE Ref and ISE Cal bottle are not calibrated correctly.	In <Diagnostics> perform <Adjust ISE Ref Bottle Sensor> and <Adjust ISE Cal Bottle Sensor>. If the error persists call service.
7100	A power fail has been detected and an automatic system restart was performed.	
7101	[%s] Rotor position error. Switch off the instrument.	Check if the rotor is blocked or jamming. Eliminate the cause. Restart the system. If the error persists call service.
7102	[%s] Transfer bumper init failed. Perform restart.	
7103	[%s] Adjustment of the ISE Ref bottle or ISE Cal bottle weight sensor failed.	Repeat the adjustment: In <Diagnostics> perform <Adjust ISE Ref Bottle Sensor> and <Adjust ISE Cal Bottle Sensor>. If the error persists call service.
7107	[%s] A not specified hardware error (%d) was reported by the ISE Unit.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7108	[%s] A not specified hardware error (%d) was reported by the DC-Slave control.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7109	[%d] The sample probe is bent or not properly aligned.	Check the probe and replace it if necessary. Restart the system. If the error persists call service.
7110	[%d] A timing error occurred while fluid is expelled into a cuvette. Probably the error was caused by a previous hardware problem.	Check for previous errors. Restart the system. If the error persists call service.
7111	[%d] Transfer movement failed due to open cover.	Keep covers closed while the system is in Operating status.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
7112	[%s] The ISE reference sensor detected air when ISE Ref solution was transported.	Check the ISE Ref bottle filling level. Perform <Prime ISE Reference and Calib.> and check the fluid flow. If the error persists call service.
7113	[%d] A prime cycle failed due to an open cover.	Ensure that all covers are closed while the system is being initialized, in the Operating or Maintenance status.
7114	[%d] An initialization error occurred. The X-transfer zero positions are invalid.	Check the X-transfer for obstructions. Ensure that all covers are closed. Restart the system. If the error persists call service.
7115	[%d] Dispensing into the ISE tower stopped because the ISE tower was not empty.	Check the ISE tower waste tubing. Check the ISE tower outlet for obstructions. Check the pinch valves. If the error persists call service.
7116	[%d] The needle crashed while the system was trying to dispense fluid.	Switch off the instrument. Check if the transfer or probe movement is obstructed. Restart the system. If the error persists call service.
7117	[%d] Consequential error caused by a previous hardware or software problem.	Check previous errors. Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7118	[%s] Rotor initialization error. The light barrier did not react.	Switch off the instrument. Remove the rotor and clean the light barrier. Reinstall the rotor. Restart the system. If the error persists call service.
7119	[%d] Consequential error caused by a previous hardware or software problem.	Check previous errors. Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7120	[%s] Either a rotor, an X-transfer or a Z-transfer position error occurred. Maybe one of these devices has been moved manually by accident.	Restart the system. If the error persists call service.
7121	[%d] Consequential error caused by an internal communication problem.	Check previous errors. Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7122	[%d] The Prepare action has been stopped due to an open cover.	Ensure that all covers are closed while the system is being initialized, in the Operating or Maintenance status.
7123	Extra wash cycle after reagent pipetting failed.	Perform <Deproteinize Probe> before next run.
7124	Analyzer temperature outside the range.	
7125	[%s] Motion control error in rotor motor.	Restart the system to correct the problem. If the error persists call service.
7126	[%s] Motion control error X-transfer motor.	Restart the system to correct the problem. If the error persists call service.
7127	[%s] Motion control error Z-transfer motor.	Restart the system. If the error persists call service.
7128	[%s] Initialization error X-transfer.	Switch off the instrument. Ensure that all covers are closed. Check if the X-transfer is blocked or jamming. Restart the system. If the error persists call service.
7129	[%s] Initialization error Z-transfer.	Switch off the instrument. Check if the Z-transfer is blocked or jamming. Check the seating of the transfer head cover. Restart the system. If the error persists call service.
7130	[%s] Rotor position error.	Switch off the instrument and check if the rotor is blocked or jamming. If the error recurs call service.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
7131	[%s] Position error X-transfer.	Switch off the instrument and check if the X-transfer is blocked or jamming. If the error recurs call service.
7132	[%s] Initialization error Z-transfer.	Switch off the instrument. Check if the Z-transfer is blocked or jamming. Check the seating of the transfer head cover. Restart the system. If the error persists call service.
7133	[%s] Rotor motor overheated.	Switch off the instrument. Check if the rotor is blocked or jamming. Restart the system. If the error persists call service.
7134	[%s] Motor X-transfer overheated.	Switch off the instrument. Check if the X-transfer is blocked or jamming. Ensure that the X-transfer can be moved smoothly. Restart the system. If the error persists call service.
7135	[%s] Motor Z-transfer overheated.	Switch off the instrument. Check if the Z-transfer is blocked or jamming. Ensure that the Z-transfer can be moved smoothly. Restart the system. If the error persists call service.
7136	[%s] Tube bottom detector is blocked or jamming.	Switch off the instrument. Remove the transfer head cover. Check the tube bottom detector mechanism. Install the transfer head cover. Restart the system. If the error persists call service.
7137	[%s] Na sample measurement unstable.	Check the expiry date of the Ref and Na electrodes. Replace expired electrodes. Check the ISE tubing for obstructions and leaks. Perform <Electrode Service>. If the error persists call service.
7138	[%s] Cl sample measurement unstable.	Check the expiry date of the Ref and Cl electrodes. Replace expired electrodes. Check the ISE tubing for obstructions and leaks. Perform <Electrode Service>. If the error persists call service.
7139	[%s] K sample measurement unstable.	Check the expiry date of the Ref and K electrodes. Replace expired electrodes. Check the ISE tubing for obstructions and leaks. Perform <Activate Electrodes>. If the error persists call service.
7140	[%s] Na calibrator measurement unstable.	Perform <Electrode Service> and <Prime ISE Reference and Calib.>. Check ISE Cal and Ref flow. Check the ISE tubing for obstructions. If the error persists call service.
7141	[%s] Cl calibrator measurement unstable.	Perform <Electrode Service> and <Prime ISE Reference and Calib.>. Check ISE Cal and Ref flow. Check the ISE tubing for obstructions. If the error persists call service.
7142	[%s] K calibrator measurement unstable.	Perform <Electrode Service> and <Prime ISE Reference and Calib.>. Check ISE Cal and Ref flow. Check the ISE tubing for obstructions. If the error persists call service.
7143	[%d] An internal software problem (%d) occurred. The access to the internal EEPROM failed.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
7144	[%d] The instrument battery is low or not connected. The date and time may no longer be valid. A replacement of the battery is probably required.	Call service.
7145	[%d] The action <Clean ISE> has been stopped due to an open cover.	Ensure that all covers are closed while the system is being initialized, or in the Operating or Maintenance status.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
7146	[%d] The initialization of the system has been stopped due to an open cover.	Ensure that all covers are closed while the system is being initialized, or in the Operating or Maintenance status.
7147	[%d] The initialization of the ISE Unit has been stopped due to an open cover.	Ensure that all covers are closed while the system is being initialized, or in the Operating or Maintenance status.
7148	[%d] Initialization of the ISE Unit has been stopped due to a blocked transfer.	Switch off the instrument. Check if the transfer is blocked or jamming. Ensure that all covers are closed. Restart the system. If the error persists call service.
7149	[%d] Initialization of the rotor failed. The calculated offset is outside the range.	Switch off the instrument. Check if the rotor is blocked or jamming. Restart the system. If the error persists call service.
7150	[%d] Initialization of the transfer failed due a level detection problem.	Switch off the system. Clean the probe and probe holder and ensure that they are installed correctly. Restart the system. If the error persists call service.
7151	[%d] Dispensing fluid into the ISE tower failed due to an incorrect X-transfer or probe position.	Switch off the instrument. Check if the X- transfer and Z-transfer are blocked or jamming. Restart the system. If the error persists call service.
7152	[%d] A pipetting or dispensing cycle failed due to an incorrect X-transfer or probe position.	Switch off the instrument. Check if the X- transfer and Z-transfer are blocked or jamming. Restart the system. If the error persists call service.
7153	[%d] A reagent mixing cycle failed because the probe crashed.	Switch off the instrument. Check if the probe and probe holder are correctly installed. Replace a bent probe. Restart the system. If the error persists call service.
7154	[%d] A probe wash cycle failed because the probe crashed.	Switch off the instrument. Check if the probe and probe holder are correctly installed. Replace a bent probe. Restart the system. If the error persists call service.
7155	[%d] Initialization of the transfer failed because the probe crashed.	Switch off the instrument. Check if the probe and probe holder are correctly installed. Replace a bent probe. Restart the system. If the error persists call service.
7156	[%d] A prime cycle failed because the probe crashed.	Switch off the instrument. Check if the probe and probe holder are correctly installed. Replace a bent probe. Restart the system. If the error persists call service.
7157	[%d] Initialization of the Z-transfer failed due to a level detection problem.	Switch off the instrument. Check if the probe and probe holder are correctly installed. Clean the init plate. Restart the system. If the error persists call service.
7158	[%d] A tube bottom sensor problem was detected.	Switch off the instrument. Check if the tube bottom sensor mechanism can be moved freely. Restart the system. If the error persists call service.
7159	[%d] Movement stopped because the probe crashed.	Switch off the instrument. Check if the probe and probe holder are correctly installed. Replace a bent probe. Check the magnetic slider. Restart the system. If the error persists call service.
12001	The host computer did not answer the order query for sample %s within the time limit.	Check the communication and existing orders on the host.
12002	The communication port is not accessible. Communication to the host server is not possible.	Check the Host Settings and compare them with the host server settings.
12003	Sending a message to the host computer failed.	Enable the host trace file in the Host Settings in order to record HIF communication activities.
12004	Receiving or processing a message from the host computer failed.	Enable the host trace file in the Host Settings in order to record HIF communication activities.

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
12005	Host server could not send message to the host.	Select result and perform Retransmit. If the problem recurs enable the host trace file in the Host Settings. Retransmit again and export the log files. If the error persists call service.
12006	Changes of the host communication settings could not be applied.	Restart the system. If the error persists call service.
13001	A software error (%d) occurred. The database could not be opened.	Restart the system. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
13002	A software error occurred. The calculated result for the order (%d) could not be stored in the database.	Export the log files. If the error persists call service.
13003	A software error occurred. Data of the order (%d) could not be retrieved from the database.	Export the log files. If the error persists call service.
13004	A software error occurred. The required parameters for application (%d) could not be found.	Export the log files. If the error persists call service.
13005	A software error occurred. The calibration result for order (%d) could not be stored in the database.	Export the log files. If the error persists call service.
13006	A software error occurred. A required parameter set for a certain application (%d) could not be found.	Export the log files. If the error persists call service.
13007	Reagent disc %d was replaced by disc %d while the system was switched off.	Ensure that the information provided in <Disk Status> corresponds to the actually loaded reagent bottle sets.
13008	The import of the database failed. The database version does not correspond to the currently installed software version. An old database version was provided (detected V %d ; expected V %d).	
13009	A software error occurred. An invalid database entry (%d) for a control was detected.	Export the log files. If the error persists call service.
13010	A software error occurred. An invalid database entry (%d) for a control was detected.	Export the log files. If the error persists call service.
13011	Validation of Development Channels failed. The number of installed DC applications does not match the number of available channels. (%d DC applications found, %d channels installed).	
13012	Auxiliary reagent (%d) not found.	Ensure that the reagent bottle has been loaded. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
13013	Reagent bottle %d not found.	Ensure that the reagent bottle has been loaded. If the error recurs export the log files with the system remaining in this error condition. If the error persists call service.
13014	Calibrator lot definition for application %d inconsistent. Check number of standards used with number of calibrator cups and Last Is Water definition.	
20001	<Replace Water Inlet Filter> completed.	
20002	<Clean Water and Waste> completed.	
20003	<Replace Photometer Lamp> completed.	
20004	<Clean Probe Manually> completed.	
20005	<Prime Fluid System> completed.	
20006	<Clean Housing> completed.	

Table D-1 List of alarm messages (Continued)

ID	Message	Comment
20007	<Deproteinize Probe> completed.	
20008	<Clean Reagent Disk> completed.	
20009	<Database Backup> completed.	
20010	<Call Service Rep.> completed.	
20011	<Clean ISE Tower Manually> completed.	
20012	<Replace ISE Unit Tubing> completed.	
20013	<Replace ISE Pump Tubing> completed.	
20014	<Replace ISE %s Electrode> completed.	
20015	<Initialize ISE Reference Sensor> completed.	
20016	<Clean ISE Tower Automatically> completed.	
20017	<Initialize ISE Unit> completed.	
20019	<Electrode Service> completed.	
20020	<Activate Electrodes> completed.	
20021	<Prime ISE Reference and Calibrator> completed.	
20022	<Condition ISE Tubing> completed.	
20023	An unknown action %d was completed successfully.	
20024	Installation completed. The intervals of the maintenance actions were reset successfully (except daily maintenance actions).	
20025	<Abs. Air/Water Calibration> completed.	
20026	The external water reservoir was refilled.	
20027	The external waste container was emptied.	
20028	<Daily Prepare Actions> completed.	
20029	Database cleanup completed.	
20030	<Initialize Degaser Fluid Sensor> completed.	

Table D-1 List of alarm messages (Continued)

Result flags

In this chapter, you will find a list of the flags generated by the **cobas c** 111 instrument, their associated error messages, and the possible user actions.

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About flags

Flags are automatically generated with results if during processing certain technical checks were not passed or if the result exceeds or does not reach predefined limits.

Measurements that did not generate flags can be considered technically correct.

Flags are displayed and printed with the results.

► To display flag information

1 Display the result.

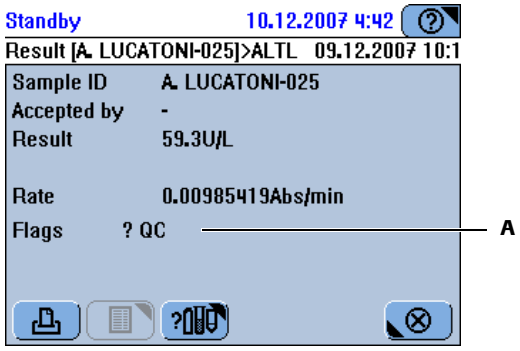
Do one of the following:

If	Do this
You want to look at sample results:	Choose **Workplace** > **Result Review**
You want to look at calibration results:	Choose **Workplace** > **Calibrations**
You want to look at QC results:	Choose **Workplace** > **QC Status**

A screen is displayed that lists the results. If flags were generated, the flag with the highest priority is displayed. For ratio results, the flag with the highest priority of all constituent test results is displayed.

2 Select the flagged result.

3 Press [🔍] to display all flags that were generated for this test (A). They are sorted according to their priority.



4 Look up the flag in section *List of flags* on page D-28 for detailed information on the flag.

■

► To display flag information with the sample still on board

1 Choose **Overview** > tube button.

A screen is displayed that shows the result, together with the flag of the highest priority.

👁 To view all flags that were possibly generated see *To display flag information* on page D-25.

■

Flags and error messages

Some flags trigger error messages if they appear in consecutive measurements. Each flag has its own counter. If one measurement does not generate the flag, the counter is reset to zero.

Flag priority

If the conditions in the **cobas c**111 instrument are such that multiple flags were generated for a single measurement, only the flag with the highest priority is displayed in the results lists.

Flags and user actions

With each flag description contained in this chapter, the recommended user actions are given.

See *List of flags* on page D-28.

Safety

Before you start troubleshooting, it is essential that you both read and understand the safety information listed below.

Read carefully all safety notices given in instructions and make sure you understand them.

WARNING

Injury through working solutions

Direct contact with cleaning solutions or other working solutions may cause personal injury. When handling such solutions, exercise the precautions required for handling them, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics cleaning solutions.

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Personal injury or damage to the analyzer due to contact with instrument mechanism

Do not touch moving parts during instrument operation.

Incorrect results or damage to the analyzer due to wrong operation

Operators are required to have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Start all maintenance actions on the screen. Do not perform maintenance actions without the assistance of the user interface.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to trained service representatives.
- Follow standard laboratory practices, especially when working with biohazard material.

Where a flag description gives a list of recommended actions, work through each step in turn until you have solved the problem. Proceed to the next step only after you have completed the previous one.

List of flags

This section lists the general flags and those that concern absorbance measurements only, and it provides information on each of the flags.

For information on ISE-specific flags, see *List of ISE flags* on page E-71.

>

Meaning Result generated by re-performing the test with the same running parameters (repeated).

Message ID 120

Priority 32

Possible cause The user initiated the repeat.

Recommended actions No action required.

V

Meaning A rerun result with diluted sample.

Message ID 121

Priority 33

Possible cause The user initiated the rerun.

Recommended actions No action required.

Ag Excess

Meaning Antigen excess.

The sample contains an excess antigen and a valid result cannot be calculated.

Message ID 6

Priority 19

Recommended actions Rerun the test with postdilution.

? Cal

Meaning A result where its calibration is flagged.

Message ID 110

Priority 29

Possible cause The calibration was in question and has been flagged, however the calibration could be used to calculate the result (compare with Cal Error where the calibration did not provide a usable result).

Recommended actions Check and redo calibration if needed.

Cal Error

Meaning No valid calibration data available.

Message ID 43

Priority 24

Possible cause Caused by an alarm that occurred during calibration because the calibration could not provide a usable result.

Recommended actions Check the flags of the calibration and proceed to deal with the calibration first.

Calc Error

Meaning Calculation error.

- General calculation error.
- Slope or nonlinear standard curve cannot be calculated due to a calibration error.

Message ID 16

Priority 13

Possible cause

- Calibrator outdated or deteriorated.
- Misplacement of the calibrator tubes.

Recommended actions

- Repeat calibration with fresh calibrators.
- If the calibrators were incorrectly positioned, replace the calibrators and repeat the calibration.

Curv Dir

Meaning Curve direction.

The direction of the calibration curve is incorrect or not as expected.

Message ID 14

Priority 10

Possible cause Misplacement of calibrator tubes

Recommended actions

1. Check the details of the calibration.
2. If the calibrators were incorrectly positioned, replace the calibrators correctly and rerun the calibration.

Ep Unstab

Meaning End point unstable.

The absorbance values near the endpoint show unacceptable fluctuation.

Message ID 9

Priority 8

Recommended actions

CAL

1. Repeat with fresh calibrators if only calibration is flagged.
2. If the flag is on control, sample, or on calibration repeat results, replace the reagent set.

CNTL

1. If only one control is flagged, repeat with fresh control.
2. If more than one control and sample result is flagged, replace the reagent set.

TEST

1. Rerun diluted.
2. If only one sample result is flagged, repeat with fresh sample.
3. If more than one sample result is flagged or a repeat result, replace the reagent set.
4. If a serum protein test result is flagged, repeat with dilution.

High Abs

Meaning Excessive absorbance.

The absorbance value to be used for calculation and checks is > 2.0 Abs.

Message ID 5

Priority 1

Recommended actions CAL

- Repeat with fresh calibrator.

CNTL

- If a single control is flagged, rerun with a fresh control.
- If more than one control is flagged, perform a calibration.

TEST

- If a single sample result is flagged, rerun with dilution.
- If the problem persists, replace the reagent set.

High Act

Meaning High activity.

- The absorbance change during measurement is above the accepted limit, i.e. the reaction has taken off too fast.

Message ID 56

Priority 9

Recommended actions CAL

1. Check if the correct calibrators are placed on the instrument.
2. Repeat with fresh calibrators.

CNTL

1. Check control. Repeat with fresh control.

TEST

1. Rerun with dilution.

< Kin Read

Meaning Insufficient kinetic reading points.

Message ID 11

Priority 11

Possible cause
- Not enough kinetic readings.
- Insufficient absorbance readings were found in the linear part of the reaction to be able to calculate a rate.
- Not enough readings in kinetic range for calc mode Kinetic.

Recommended actions

CAL

1. Check reaction plot.
2. Repeat with fresh calibrator.

CNTL

1. Check reaction plot.
2. Repeat with fresh control.

TEST

1. Check reaction plot.
2. Rerun with dilution or concentration if necessary.

Low Act

Meaning Low activity.

This check is used to identify zero pipetting for samples and reagents.

- The absorbance change during measurement is below the accepted limit, i.e. the reaction has taken off too slowly. Possibility of substrate exhaustion.
- The absorbance change during the measurement is lower than the defined limit.

Message ID 56

Priority 9

Recommended actions

CAL

1. Check if the correct calibrators are placed on the calibrator rack.
2. Repeat with fresh calibrators.

CNTL

1. Check the control. Repeat with fresh control.

TEST

1. Rerun with dilution.

Non Linear

Meaning Abnormal linearity.

Message ID 11

Priority 11

Possible cause
- The slope changes between the first and last parts of the reaction curve.

Recommended actions

CAL

1. Check reaction plot.
2. Repeat with fresh calibrator.

CNTL

1. Check reaction plot.
2. Repeat with fresh control.

TEST

1. Check reaction plot.
2. Rerun with dilution or concentration if necessary.

Non Mono

Meaning Curve not monotonic.

No calibration curve could be calculated because the rates of the calibrators were non-monotonic.

Message ID 80

Priority 14

Possible cause Misplacement of a series of calibrators, automatic dilution series failed.

Recommended actions
1. If the calibrators were incorrectly positioned, re-place the calibrators correctly and rerun the calibration.
2. Check the fluid system
3. Repeat the calibration

Out of Rng

Meaning Curve out of range.

The calibration curve is outside the acceptable/ programmed range.

Message ID 84

Priority 16

Possible cause Deteriorated or outdated calibrator or reagent.

Recommended actions
1. Repeat with fresh calibrators.
2. If the calibrators were incorrectly positioned, re-place the calibrators correctly and repeat the calibration.
3. If flag reoccurs, repeat with fresh reagent.

? QC

Meaning A result where the quality control measurement is flagged.

Message ID 111

Priority 30

Possible cause The last QC measurement before this measurement was flagged. The dependency is derived from the time sequence.

Recommended actions Check QC measurement.

R 1(2.5s)

Meaning One control value is above 2.5 standard deviation or below -2.5 standard deviation.

Message ID 36

Priority 28

Possible cause
- The reagent has deteriorated (linearity of working curve degraded).
- One control is concentrated or has deteriorated.

Recommended actions
1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check the calibration and reagent status. Repeat with fresh reagent.

R 1(3s)

Meaning One control value is above 3 standard deviation or below -3 standard deviation.

Message ID 35

Priority 27

Possible cause
- Improper control is set.
- Proper control values (mean value, standard deviation) are not specified.

Recommended actions
1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check the calibration and reagent status. Repeat with fresh reagent.

>R 2(2s)

Meaning Two sequential control measurements are above the 2 standard deviation.

Message ID 29

Priority 26

Possible cause
- The controls are not properly prepared.
- The controls are not properly positioned on the instrument.

Recommended actions
1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check the calibration and reagent status. Repeat with fresh reagent.

<R 2(2s)

Meaning Two sequential control measurements are below the -2 standard deviation.

Message ID 29

Priority 26

Possible cause
- The controls are not properly prepared.
- The controls are not properly positioned on the instrument.

Recommended actions
1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check the calibration and reagent status. Repeat with fresh reagent.

>Reag Rng

Meaning Absorbance above defined reagent range.

- During calibration, the absorbance value of the lowest calibrator is above the upper defined range.

Message ID 12

Priority 7

Possible cause Deteriorated or outdated calibrator or reagent.

Recommended actions
1. Check the calibration and reagent expiry dates.
2. Repeat with fresh lowest calibrator.
3. If the flag reappears, replace reagent set (a reagent may be contaminated).

<Reag Rng

Meaning Absorbance below defined reagent range.

- During calibration, the absorbance value of the lowest calibrator is below the lower defined range.

Message ID 12

Priority 7

Possible cause Deteriorated or outdated calibrator or reagent.

Recommended actions
1. Check the calibration and reagent expiry dates.
2. Repeat with fresh lowest calibrator.
3. If the flag reappears, replace reagent set (a reagent may be contaminated).

> Repl Dev

Meaning Greater than replicate deviation.

Deviation between replicates exceed programmed limit. One or more replicates are erroneous.

Message ID 13

Priority 12

Possible cause Problems in air/water system, air bubbles, clogged probe.

Recommended actions
1. Check the calibrators for air bubbles and repeat the calibration.
2. If the flag reappears, repeat with fresh calibrators.
3. Check the probe.
4. Check the fluid system.

> RR

Meaning Above reference range.

For patient samples, the calculated concentration is greater than the upper limit of the expected value range.

nnnnn is the actual value that was checked against.

Message ID 40

Priority 22

Recommended actions No action required.

< RR

Meaning Below reference range.

For patient samples, the calculated concentration is less than the lower limit of the expected value range.

nnnnn is the actual value that was checked against.

Message ID 41

Priority 23

Recommended actions No action required.

> Std Dev

Meaning Greater than standard deviation.

A point in the calibration fell outside the defined limits.

Message ID 17

Priority 17

Recommended actions

1. Check calibration curve.
2. Repeat with fresh calibrators.
3. If the calibrators were incorrectly positioned, replace the calibrators correctly.

> Test Rng

Meaning PANIC value over (upper) Technical Limit.
The result is higher than the upper limit for the test.

Message ID 26

Priority 20

< Test Rng

Meaning PANIC value below (lower) Technical Limit.
The result is lower than the lowest limit for the test.

Message ID 27

Priority 21

Troubleshooting

Dealing with exceptional situations

In this chapter, you will find information on how to deal with selected exceptional situations.

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- Checking the printer status D-46
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- Realigning the reagent disk D-50
- Exporting diagnostics screens to USB D-51

Introduction

Effective troubleshooting requires a good understanding of all basic operating procedures for the **cobas c** 111 instrument and the system software.

Preventive maintenance

You can avoid most unforeseen situations if you observe the recommended procedures at all times and if the operating environment is effectively controlled by performing all maintenance actions when they become due in the manner described in the Operator's Manual.

See *Maintenance actions* on page C-8.

Information about the status of the system

The system performs numerous checks. When a certain event has occurred or when an irregularity is detected, a message is generated. Messages are displayed in two ways:

- Immediate feedback on user actions is displayed in a *pop-up message screen*.

  See *Message screen* on page D-5.
- Information concerning a problem that occurred during operation is reported as *alarm messages* in the *alarm monitor*.

  See *Alarm monitor* on page D-6.

Dealing with exceptional situations

The following table list possible exceptional situations, provides information on the possible causes, and suggests ways of remedying the situation. (Subsequent sections contain detailed procedures for selected remedies.)

Situation	Affected items	Possible causes	Comments
Measuring whole blood.	Tube bottom detection	Use of unsuitable tubes.	With whole blood samples, pipetting is always performed from near the tube bottom of the tube. To ensure proper pipetting, only use primary tubes. With other tubes, the bottom detector might register and pipetting would stop.
The fluid connectors need to be disconnected from the instrument.	External fluid connectors.	• Moving the instrument to another location. • Removing blockages.	To get easier access to the release clamps on the connectors, remove the side panel before removing the connectors. 👁 See *To disconnect a tube from the instrument* on page B-129.
A service representative asks you to perform diagnostics tasks.	Diagnostics features.	These features are usually used at the request of a service representative.	Follow the instructions given by the service representative. 👁 See *Exporting diagnostics screens to USB* on page D-51.
The system does not work or does not switch on and the power switch light is off.	Instrument.	No electricity.	1. Check that the instrument is connected to the mains power supply. 2. If the instrument is properly connected replace the mains fuses. 👁 See *Changing the mains fuses* on page D-47.
No printing.	Printer.	Printer is out of paper.	Load printer paper. 👁 *Refilling printer paper* on page B-122.
		Printer jam.	👁 *To clear the paper jam* on page D-46.
Reagent disk cannot be inserted in the reagent cooler.	Reagent disk.	The bottle storage assembly in the reagent disk was moved while the latter was outside the instrument.	The reagent disk is designed to handle reagents while it is loaded on the instrument. The cover is equipped with a locking mechanism. Always remove and load reagents while the reagent disk is on the instrument and by using the software supported procedures. 1. Align the bottle storage assembly in the reagent disk. 👁 See *Realigning the reagent disk* on page D-50. 2. Insert the reagent disk in the cooler.

Figure D-4 Troubleshooting overview

Situation	Affected items	Possible causes	Comments
The system does not go to **Operating** status.	System status	There are not enough free cuvettes on the instrument.	Load empty cuvette segments. See *Preparing cuvettes* on page B-28.
		Air/water calibration is required.	Perform **Abs. Air/Water Calibration** maintenance action. See *Perform an air/water calibration* on page C-28.
		In the corresponding calibrator lot definitions of at least one of the tests you want to perform, the value for **Last Is Water** is **Off**.	The **Last Is Water** definition defines what is used as the zero calibrator. It is either system water (**On**) or a standard, usually water (**Off**), which would be placed in a tube like any other calibrator. With some tests, calibration does not work with special zero calibrators, they need the **Last Is Water** definition on. Possible remedies: 1. Delete the current calibration order and redefine it. 2. If the **Last Is Water** definition is **Off**, make sure to place a special zero calibrator on the instrument when calibrating. (This is usually water.) If this does not help change the **Last Is Water** value to **On**. (Calibration for this test does not work with a special zero calibrator.) 1. Choose **Workplace** > **Lot Data** > **Calibrators**. 2. Select the entry for the test and expand the entry. 3. Select the **Last Is Water** entry and press . 4. Press **On**. 5. Press . 6. Delete the current calibration order and redefine it.
		A hardware error had occurred.	Some hardware conditions prevent the system from performing tests. 1. Press to check the alarm messages. 2. Follow the advise given in the messages. 3. Choose > **Restart** to restart the system.

Figure D-4 Troubleshooting overview (Continued)

Reacting to messages

A **cobas c** 111 error message starts with a message ID, which consists of a number followed by the date and time, for example:

7009.19.19.32.1402 [25.08.2006 8:53]

Providing information to service representatives

Whenever you are asked to provide message information to a service representative, provide the error codes contained in the explanatory text, not the message ID of the first line. If there are no error codes in the text, supply the complete message text.

Also keep in mind that an event may trigger several messages, therefore it is important to provide the information for all messages that were generated within about one minute.

Basically there are three kinds of error message texts:

- Messages that contain text only.
- Messages that contain an error code of the format a.bbb.xxx, for example [3.000.121].
- Messages that contain a nine digit error code, for example [104000551].

The following table lists selected messages and provides more detailed information on how to react to them.

In the "Message or error code" column of the following table, the most relevant information is the number, the texts may be different on the actual instrument.

Message or error code	Affected items	Possible causes	Comments
1.xxx.81 1.xxx.82 1.xxx.84	Instrument.	Fuse **F1**, **F2**, or **F4** is defective.	Replace the low voltage fuse that is mentioned in the alarm message. See *Changing the low voltage fuses* on page D-49.
[109000572] code raised by IC software caused by an unexpected handling or system situation.	Instrument.	The probe is bent or the transfer head is poorly adjusted.	1. Check that the probe is mounted properly and replace it if necessary. See *Replacing the probe* on page B-125. 2. If the problem persists, contact your service representative.
No connection to Instrument Control.	Instrument.	Fuse **F3** is defective.	Check the LED of fuse F3. Replace the fuse if necessary. (If the fuse has blown, the LED is off.) See *Changing the low voltage fuses* on page D-49.
		The LAN cable is not or not properly connected.	Check that the LAN cable is properly connected: 1. Switch off the instrument. 2. If the cable was not connected, connect it. If the cable was connected, remove it at both ends and reconnect it. 3. Start the instrument.
		Electronic problem	If the above measures are not successful, contact your service representative.

Figure D-5 Troubleshooting with the help of messages

Message or error code	Affected items	Possible causes	Comments
[1.xxx.73] Level detection error (conductivity).	Level detection.	• Poor water quality. • Contamination with cleaner (valve is leaking)	1. Make sure you use the correct water quality. 👁 See *Technical specifications* on page A-66. 2. Perform the **Prime Fluid System** maintenance action. 👁 See *Prime the fluid system* on page C-11. 3. If the problem persists, contact your service representative.
[4.xxx.41] through [4.xxx.44] Various texts related to photometer Gc-0166807.	Photometer.	• Lamp defective. • Photometer lens soiled.	Do not attempt to clean the photometer lenses. 1. Replace the photometer lamp. 2. If the problem persists, contact your service representative.

Figure D-5 Troubleshooting with the help of messages (Continued)

Detailed procedures

Checking the printer status

► **To check the printer status**

1 On the **Overview** tab, press the **System status** button.

The printer button is red.

2 Scroll to display the Printer entry.

■

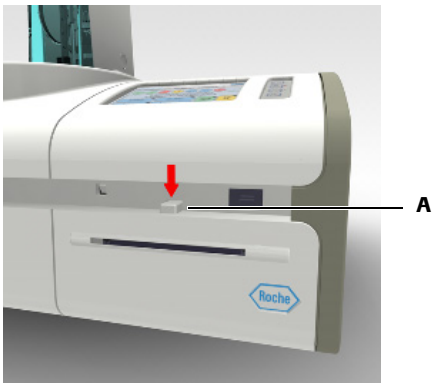
Clearing a paper jam

► **To clear the paper jam**

1 Choose > **Stop Printing**, if required.

2 Open the printer panel.

Press down the release button (A) firmly *before* you pull the panel. The panel should open without resistance.



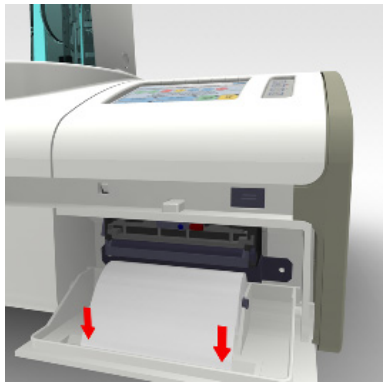
3 Lift the printer paper roll from its holder.

4 Remove all loose paper. (Cut or tear it off).

5 Place the roll back on the holder.

Make sure the paper unrolls at the top and towards you.

6 Insert the paper in the slot in the printer panel and pull some through.



7 Close the printer panel.

The system feeds some paper and then automatically resumes printing.

8 Choose **Overview** > .

9 The printer button should now be green, and the status description should be **OK**.

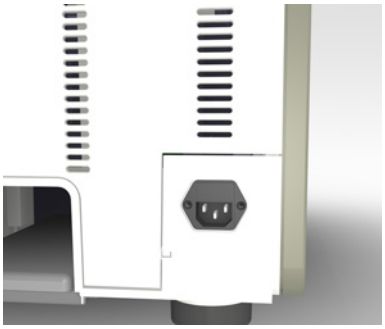
■

Changing the mains fuses

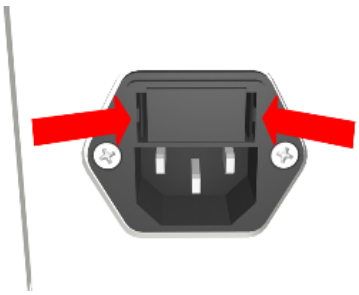
► **To change the mains fuses**

1 Press O on the main toggle switch to switch off the instrument.

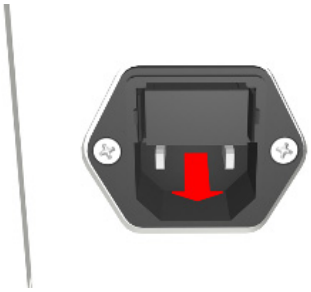
2 Disconnect the mains cable from the instrument.



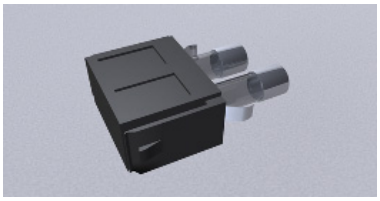
3 Using a screwdriver disengage the clips on both sides of the fuse box cover.



4 Remove the holder.



5 Remove the two fuses from the holder.



6 Replace both fuses.

Damage to the analyzer due to use of wrong fuses

Always replace fuses with new ones of the same type and specifications.

See *Technical specifications* on page A-66.

7 Insert the fuse holder in the fuse box.

Press it in firmly until the clips engage.

8 Connect the mains cable to the instrument.

9 The instrument switch should be illuminated.

■

Changing the low voltage fuses

► To change a low voltage fuse

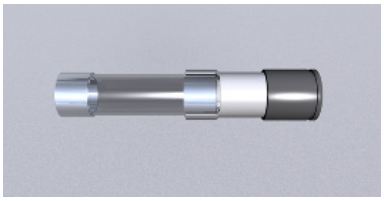
1 Switch off the instrument.

2 Using a screwdriver size 2 or 3, remove the fuse indicated in the alarm message.

A Low voltage fuses **B** Slot in low voltage fuse holder

Figure D-6

- Insert the screwdriver in the slot and turn anticlockwise until the holder disengages.
- Remove the holder with the fuse.



3 Remove the fuse from its holder.

4 Insert the new fuse in the holder.

NOTICE

Damage to the analyzer due to use of wrong fuses

Always replace fuses with new ones of the same type and specifications.

See *Technical specifications* on page A-66.

5 Insert the holder in the socket.

6 Using the screwdriver, lock the holder in position by pressing it in and turning the screwdriver clockwise until the slot is vertical.

7 Switch on the instrument.

■

Realigning the reagent disk

► To realign the reagent disk

1 Insert your fingers in the holes in the reagent disk cover an lift the reagent disk.

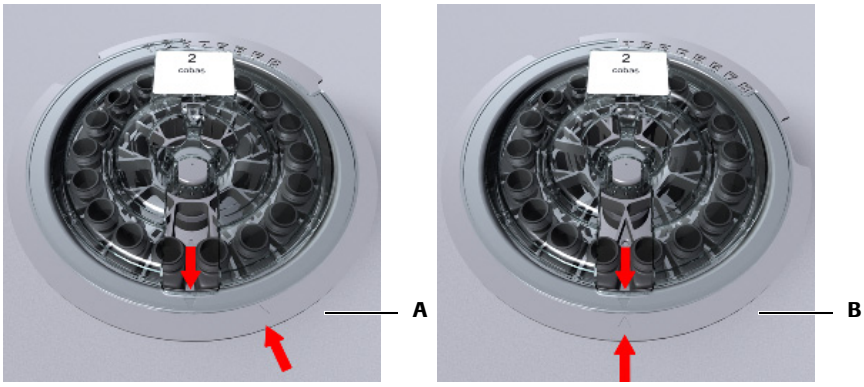
CAUTION

Spillage through tipping reagent disk

When handling the reagent disk, make sure not to tilt it.

2 Insert a pencil in the opening in the center of the underside of the reagent disk.

3 Turn the reagent disk until the arrows of the reagent disk and the cover face each other.



A Incorrect position: The two arrows do not face each other.

B Correct position: The two arrows face each other.

Figure D-7

■

Exporting diagnostics screens to USB

When performing diagnostics actions you can export the content of the screen to the USB stick.

Prerequisites You need **Lab Administrator** or **Administrator** user rights to perform diagnostics actions, and the system must be in **Standby** or **Stopped** status.

► To export the content of the screen

1. Press ⊙ to start the diagnostics action.
2. Press 🖶.
3. Press **Send to File**.

   As screen is displayed, asking you to insert the USB stick.
4. Insert the USB stick.
5. Press ✓.
6. Select the directory.
7. Press ✓ to confirm the selection.

   The data are copied to the USB stick. (File name format: prt_yyyymmddhhmmss.txt.)

■

ISE E

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ISE description

Overview of the ISE unit

In this chapter, you will find a general overview of the **cobas c** 111 ISE unit. You also will find a description of the main components and their principle operation.

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Hardware E-9
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Overview

The Ion-Selective Electrode (ISE) module is a measurement system for electrolytes that runs independently of the main instrument. The ISE unit uses the same samples and sample tubes that are used for photometric measurements, and the samples are transferred using the same probe. The ISE unit uses specific solutions, some of which are kept in bottles on the ISE unit itself, the others are transferred to sample tubes and placed on the sample area.

Abbreviations

The following ISE specific abbreviations are used:

Abbreviation	Definition
CL-I	Chloride indirect
CL-U	Chloride urine
F	Solution 1 factor
K-I	Potassium indirect
K-U	Potassium urine
mV	Measured voltage in millivolt
NA-I	Sodium indirect
NA-U	Sodium urine
S	Slope in mV/dec
Std 1/1	First measurement of ISE Solution 1
Std 1/2	Second measurement of ISE Solution 1
Std 2	Measurement of ISE Solution 2

Measuring modes

The ISE unit makes, in serum, plasma and urine, quantitative determinations of the following electrolytes:

- Sodium (Na^+)
- Potassium (K^+)
- Chloride (Cl^-)

Measurements are done using *indirect* mode. The samples, controls, and standard solutions are diluted with system water 1:6 (1+5). The dilution and mixing are performed automatically in the ISE tower.

Pipetting volumes

Sample: 15 µL

Diluent (H2O): 75 µL

ISE measurements

ISE measurements and photometric measurements can be carried out at the same time and are independent of each other. (ISE measurements do not use cuvettes, the reagent rotor, or the photometer.) All requested ISE measurements on a specific sample, control, or standard solution are performed in parallel, that is, measurements are made at each electrode at the same time.

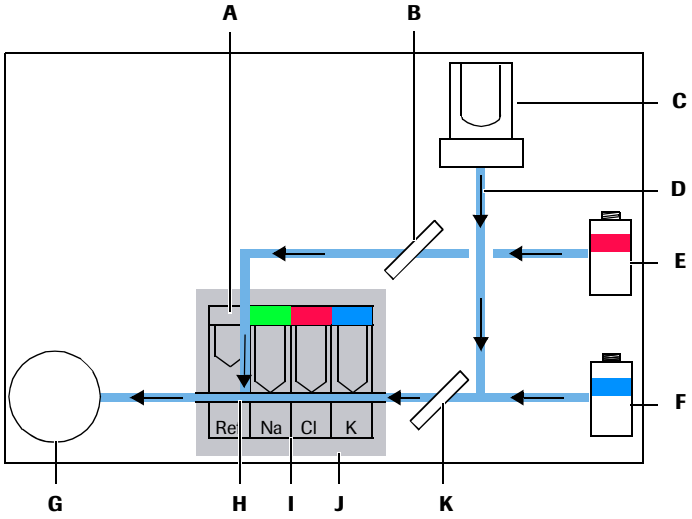
Principles of operation

The ISE unit uses flow-through ion-selective electrodes and a reference electrode with an open liquid junction. Each electrode has a membrane that is sensitive to a particular type of ion.

Measuring process

1. The ISE maintenance and standard solutions (ISE Deproteinizer, ISE Etcher, Activator, and ISE Solution 1 and 2) are pipetted from sample tubes on the sample area to the ISE tower as required.
2. The sample is pipetted from the sample tube (located on the sample area) into the ISE tower. The sample is diluted with system water. Mixing is performed with four air jets arranged in a circle. These jets blow air into the tower to produce a homogenous mixture.
3. The sample is divided into segments with the aid of a special arrangement of valves. The first (shorter) segments are used for cleaning, these are followed by a longer segment, on which the measurements are made.
4. The sample is passed to the ion-selective electrodes by the action of the peristaltic pump.

   The exact positioning of segments is ensured by the ISE sample sensor.
5. In the meantime, the ISE tower is washed with distilled water and dried.
6. ISE Reference Solution is passed through the ISE Reference Electrode and into the measuring channel downstream of the electrodes. The ISE Reference Solution completes the electrical circuits for each electrode so that measurements can be made. While the measurements are made, the sample and ISE Reference Solution are stationary.
7. A one-point calibration is performed after each sample measurement using the ISE Calibrator indirect/urine, which is located on ISE unit.
8. The electrolyte concentration of the sample is calculated.



A ISE Reference Electrode
B ISE Reference Solution sensor
C ISE tower
D Samples, controls, ISE Solution 1 and 2, Activator, ISE Etcher, and ISE Deproteinizer
E ISE Reference Solution
F ISE Calibrator indirect/urine
G Peristaltic pump
H Measuring channel
I Ion-selective electrodes
J Electrode block
K ISE sample sensor

Figure E-1 Main parts of the ISE measuring system

ISE solutions

The ISE unit requires several specific solutions for performing the analyses and maintaining the system. They are listed in the following table.

Solution summary

Solution	Location	Use
ISE Solution 1	Sample area	Used in the two-point calibration of sodium, chloride, and potassium.
ISE Solution 2	Sample area	Used in the two-point calibration of sodium, chloride, and potassium.
ISE Calibrator indirect/urine	ISE unit	Used in the one-point calibration after each measurement. It is also used during ISE initialization and standby, and for maintenance purposes.
ISE Reference Solution	ISE unit	Used in all ISE measurements of sodium, potassium, and chloride. Also used during ISE standby.
ISE Etcher	Sample area	Used as a cleaning solution for cleaning the ISE Sodium Electrode during ISE maintenance.
ISE Deproteinizer	Sample area	Used as a cleaning solution for cleaning the probe, ion-selective electrodes, ISE tower, and tubing during ISE maintenance.
Activator	Sample area	Activates the electrodes, tubing, and the ISE tower during ISE maintenance. It is also used for the initialization of the ISE unit and for activating the probe. Roche recommend using their Activator on the **cobas c** 111 instrument. (For details see the package insert of the Activator.)
Water	External water container	Used for diluting the samples, controls, and standard solutions, and for cleaning purposes. It is also used during ISE initialization.
Sample	Sample area	Sample tubes are placed on the sample area of the main instrument and pipetted by the main instrument probe.
Waste	Internal waste tank	The waste is first pumped into the internal waste tank of the main instrument and then to the external waste container.

Table E-1 Solutions used with ISE analysis

Fluid stability

For information on the stability of fluids see the package insert of the fluid in question.

WARNING

Incorrect results due to changes in fluids

The chemical composition of ISE fluids changes over time. The assigned on-board stability is the interval within which the quality of the fluid remains within the prescribed tolerances. Using fluids whose interval has expired may lead to incorrect results.

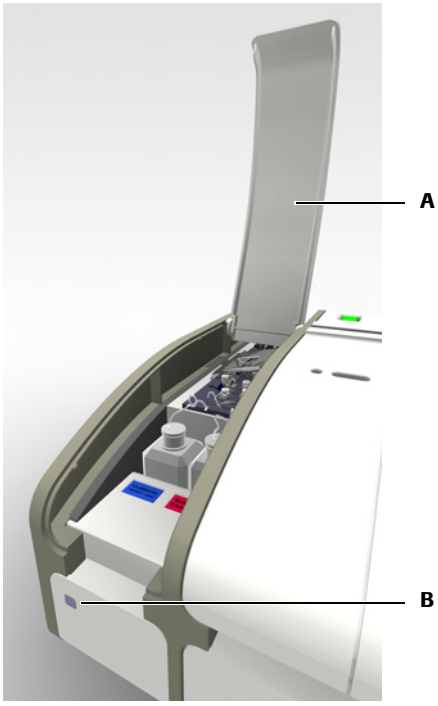
Always exchange the fluids when an interval has expired. Follow the instructions given on the screen.

Hardware

The ISE unit is designed as an add-on unit to the **cobas c** 111 main instrument. (It will be installed by your service representative.)

Panels

The ISE cover has two joints. The front cover provides access to the parts you may need to handle during daily operation. Opening the back cover as well provides access to the peristaltic pump and its tubing.



A ISE cover **B** ISE LED

Figure E-2 ISE cover

Left side panel Provides access to:

- ISE power supply
- ISE connectors

Switch off the instrument before you open this cover.

ISE cover Provides access to:

- Electrodes
- ISE unit tubing
- ISE fluid bottles

Do not open this cover when the system is in **Operating** status.

Left service flap Provides access to:

- ISE tower

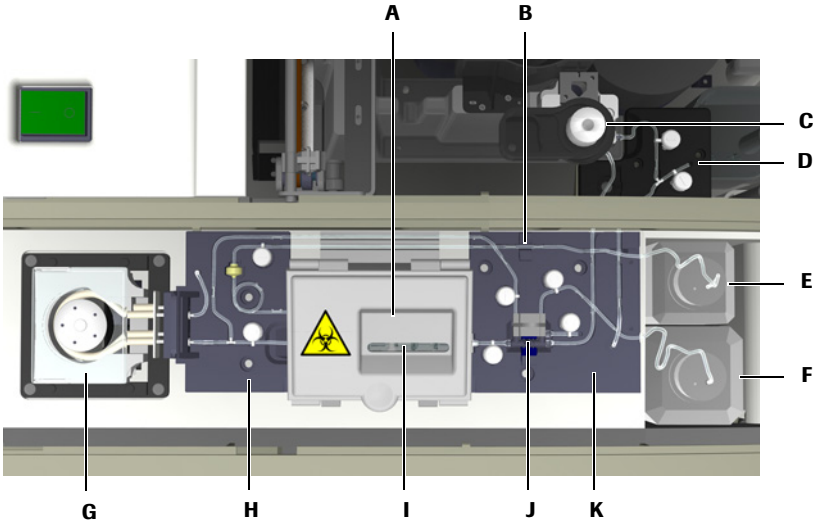
Remove this flap as instructed during maintenance actions, or switch off the instrument before you remove it.

ISE LED

The ISE LED is color coded.

		Power off (e.g. power supply disconnected.)
		The ISE unit is OK and ready for use.
	Blinking	The fluid level in the ISE Reference or ISE Calibrator indirect/urine bottle is low.
		Error, processing stopped.

Main components



A Electrode block with ISE Sodium, Potassium, Chloride, and Reference Electrode
B ISE Reference Solution sensor
C ISE tower
D Input-valve plate
E ISE Reference Solution bottle (red label)
F ISE Calibrator indirect/urine bottle (blue label)
G Peristaltic pump with pump tubing
H Exit-valve plate
I Measuring channel
J ISE sample sensor
K Entry-valve plate with tubing

Figure E-3 Main components of the ISE unit

Peristaltic pump A fluid pump that draws the solutions through the electrode block and then pumps it to the internal waste tank.

Input-valve plate A set of valves to create cleaning segments and to control the flow of waste fluids.

Entry-valve plate A set of valves to control and monitor the flow of fluids.

Exit-valve plate A set of valves to control the aspiration action of the peristaltic pump.

Electrode block A block that contains the electrodes.

ISE tower A hollow, transparent cylinder with multiple inlets and outlets for air and solutions.

In the ISE tower, samples and diluents are mixed using an air stream.

Tubing Tubing is used for transporting the fluids. It connects the ISE unit with the water and waste system, and also with the ISE Reference Solution and ISE Calibrator indirect/urine bottles, which are placed on the ISE unit.

Sensors The ISE sample sensor detects the presence of liquid (sample, control, standard solution, or ISE Calibrator indirect/urine) or air and enables the correct placing of segments for measurement and cleaning.

The ISE Reference Solution sensor detects the presence of ISE Reference Solution.

ISE fluid bottles Two bottles are placed on the ISE unit:

- ISE Calibrator indirect/urine bottle (blue label)
- ISE Reference Solution bottle (red label)

Level monitoring is performed on the basis of weight, the bottles are placed on scales.

Fluid containers

The following table shows which container is used for which fluid:

Fluid	Container(s)	Position
Samples	Tube	Sample area
Controls	Tube	Sample area
ISE Solution 1 and 2	Tube	Sample area
Cleaner	External cleaner bottle	External fluid rack
ISE Deproteinizer	Tube	Sample area
Activator	Tube	Sample area
ISE Etcher	Tube	Sample area
ISE Reference Solution	Bottle	ISE unit
ISE Calibrator indirect/urine	Bottle	ISE unit
Water	External water container	External fluid rack
Waste	External waste container	External fluid rack

Table E-2 Fluids, containers, and where they are used

The term tube includes all kinds of tubes, as long as their dimensions lay within prescribed limits. It also includes secondary tubes (cups). See *Tubes* on page A-54.

Basic operation

Operation of the ISE unit is integrated in the operation of the main instrument.

The following sections contain some ISE specific information on operation-related issues.

For general information on operating the main instrument, see the corresponding sections in Chapter 2 *Introduction to the instrument* and Chapter 6 *Daily operation*. For ISE-specific tasks, see Chapter 13 *ISE operation*.

Samples

The sample tubes are placed on the sample area of the main instrument.

Calibration

The ISE unit requires frequent calibration to ensure the accuracy of the test results obtained.

Main calibration

The electrodes are calibrated with a two-point calibration using ISE Solution 1 and 2.

The main calibration is typically performed during the Prepare phase.

One-point calibration

The electrodes are calibrated after each ISE measurement using the on-board ISE Calibrator indirect/urine. This calibration is an integral part of each ISE measurement and is performed automatically.

ISE Standby

If there is no measurement for more than three minutes, the ISE unit switches to **Standby** status. In this status, ISE Calibrator indirect/urine and ISE Reference Solution are pumped into the measuring channel and moved a short distance at regular intervals. Also, every two hours the ISE tubing is primed with ISE Calibrator indirect/urine and ISE Reference Solution. This is done to prevent the following problems:

- Flow of ISE Reference Solution backwards into the measuring channel, which can damage the electrodes because of the high ion concentration of the ISE Reference Solution.
- Crystallization of salts in the tubing, causing blockages.

The ISE unit has a separate power supply. Therefore, the **Standby** status is maintained even if the main instrument is switched off.

NOTICE

Damage to electrodes and possible tubing blockage

- Do not unplug or switch off the ISE power supply. Periodic flow of solutions must be performed at all times.
- If you intend not to use the ISE unit for more than one week, you should deactivate it. This saves ISE fluids and reduces wear and tear of the tubing. (See *Deactivating the ISE unit* on page E-64.)

Maintenance actions

Maintenance of the ISE unit is integrated in the maintenance of the main instrument. The system software guides you through the maintenance procedures.

Maintenance actions are performed after a certain event or after a defined interval has expired.

For ISE-specific maintenance actions, see Chapter 14 *ISE maintenance*.

Technical specifications

See *Technical specifications* on page A-66.

ISE operation

In this chapter, you will find information on performing the routine tasks that are required for processing tests using the ISE unit.

In this chapter *Chapter* 13

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Cleaning the ISE tower off the instrument E-36

Daily operation

Daily operation of the ISE unit is integrated in the daily operation of the main instrument.

See Chapter 6 *Daily operation*.

The following table gives an overview of the tasks you might need to perform during daily operation.

	Task	Steps	Navigation	
			With wizard	**As individual steps**
1	Starting the system	1. Switch on the system.		
2	Logging on the system			**Overview** > **Logon**
3	Preparing the system	Start the **Prepare** wizard.	**Overview** > **Prepare**	
		1. Check the external fluid containers.		**Overview** > >
		2. Check the ISE status.		**Overview** >
		3. Perform **Daily Prepare Actions**.		**Utilities** > **Maintenance**
4	Defining orders	Start the **Orders** wizard.	**Overview** > **Order** (or **Overview** > **STAT**)	
		1. Identify the sample.		n/a
		2. Select the tests.		n/a
		3. Place the sample.		n/a
		4. Start the run.		
5	Monitoring the progress		n/a	**Overview**
6	Validating results	1. View results.	n/a	**Workplace** > **Result Review**
		2. Handle flagged results.	n/a	**Workplace** > **Result Review** > ... > **Repeat** ... > **Rerun**
		3. Accept results.	n/a	**Workplace** > **Result Review** > > **Accept**
7	Performing calibrations			
	Performing individual calibrations	1. Start the wizard.	**Workplace** > **Calibrations** >	
		2. Select the test.		n/a
		3. Prepare and place the calibrators.		n/a
		4. Start the calibration.		
		5. Validate the calibration results.		**Workplace** > **Calibrations** >
		6. Remove the calibrators.		
	Performing all due calibrations	1. Start the wizard.	**Workplace** > **Calibrations** >	
		2. Select all tests with due calibrations. or Select all tests with calibration due within the forecast period.		n/a
		3. Prepare and place the calibrators.		n/a
		4. Start the calibration.		
		5. Validate the calibration results.		**Workplace** > **Calibrations** >
		6. Remove the calibrators.		

Table E-3 Overview of the daily operation tasks

	Task	Steps	Navigation	
			With wizard	**As individual steps**
8	Performing controls			
	Performing **Default QC**	1. Start the wizard.	**Overview** > **Order** > $	
		2. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		3. Start the QC measurement.		
		4. Validate the QC results.		**Workplace** > **QC Status** >
		5. Remove the controls.		n/a
	Performing an individual QC measurement	1. Start the wizard.	**Workplace** >	**QC Status** >
		2. Select a test.		n/a
		3. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		4. Start the QC measurement.		
		5. Validate the QC results.		**Workplace** > **QC Status** >
		6. Remove the control.		
	Performing all due QC measurements	1. Start the wizard.	**Overview** > **Order** >	>
		2. Select a control and place the tube. Repeat until there are no controls left on the screen.		n/a
		3. Start the QC measurement.		
		4. Validate the QC results.		**Workplace** > **QC Status** >
		5. Remove the controls.		
9	Finishing the shift	1. Check for unfinished orders.		**Workplace** > **Orders** Choose > **Not Finished**
		2. Check for non-validated results.		**Workplace** > **Result Review** Choose > **Not Accepted**
		3. Check for non-transmitted results. (If working with a host system only.)		**Workplace** > **Result Review** Choose > **Not Sent to Host**
		4. Start the **End Shift** wizard.	**Overview** > **End Shift**	
		5. Perform the daily backup.		**Utilities** > **Export** > **Database**
		6. Export the full results		**Utilities** > **Export** > **Results**
		7. Clean up the database.		**Workplace** > **Orders** > **Workplace** > **Result Review**> **Workplace** > **QC Status** > **Workplace** > **QC History** > **Workplace** > **Calibrations** >
		8. Perform the maintenance actions that are due.		**Utilities** > **Maintenance**
		9. Check the external fluid containers.		**Overview** > >
		10. Log off the system.		**Overview** > button with your user name
		11. Switch off the system (if last shift).	n/a	n/a

Table E-3 Overview of the daily operation tasks

The following sections describe the ISE-specific operation tasks.

Safety information

WARNING

Injury through reagents and other working solutions

Direct contact with reagents, cleaning solutions, or other working solutions may cause personal injury.

When handling reagents, exercise the precautions required for handling laboratory reagents, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics reagents and cleaning solutions.

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Personal injury or damage to the analyzer due to contact with instrument mechanism

Do not touch any parts of the instrument other than those specified. During operation and maintenance of the instrument, proceed according to the instructions.

Keep all covers closed, operate them as instructed on the screen.

Incorrect results or damage to the analyzer due to wrong operation

Operators are required to have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Start all maintenance actions on the screen. Do not perform maintenance actions without the assistance of the user interface.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to trained Roche support representative personnel.
- Follow standard laboratory practices, especially when working with biohazard material.

Preparing the system

Short guide

The following table provides an overview on the steps that make up the preparation process.

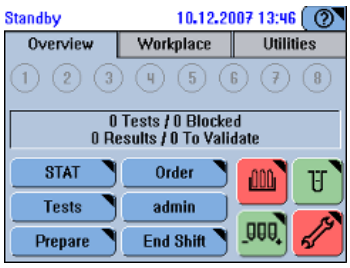
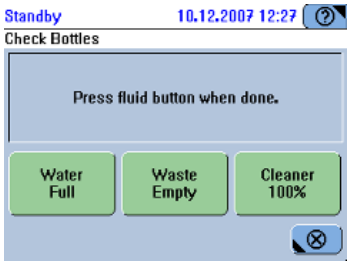
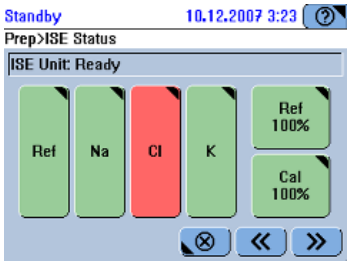
Step		User action
1	Start the Prepare wizard. 	1. On the **Overview** tab, press **Prepare**.
2	Check the status of the external containers. 	1. Refill the water container, if required, and confirm by pressing the water button. (If you refill the water, empty the waste as well.) 2. Empty the waste container, if required, and confirm by pressing the waste button. 3. Replace the cleaner bottle, if required, and confirm by pressing the cleaner button. 4. Press » to proceed to the next stage in the **Prepare** wizard.
3	Check the onboard ISE fluids. 	1. Replace the ISE fluid bottles, if required. 2. Replace the electrodes, if required. 3. Press » to proceed to the next stage in the **Prepare** wizard.
4	Perform the maintenance actions that are due.	1. Perform the **Daily Prepare Actions** maintenance action. 2. Perform the other ISE maintenance actions that are due. Perform at least all red maintenance actions.

Table E-4 Steps for preparing the system

For non-ISE-specific tasks, see *Preparing the system* on page B-12.

Starting the Prepare wizard

► **To start the preparation process**

1 Choose **Overview** > **Prepare**.

■

Checking the status of the external fluid containers

► **To check the status of the external fluid containers**

1 Follow the instructions given in *Checking the status of the external fluid containers* on page B-15.

2 When you have finished with the fluid containers, press [»] to proceed to the next stage in the **Prepare** wizard.

A screen is displayed that shows the status of the electrodes and the on-board ISE fluids.

■

When checking external fluid containers without using the Prepare wizard:

Choose **Overview** > [ ] > [ ].

Checking the ISE status

WARNING

Injury through working solutions

Direct contact with cleaning solutions or other working solutions may cause personal injury.

When handling such solutions, exercise the precautions required for handling them, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics cleaning solutions.

Replacing electrodes

► **To replace an electrode**

1 Follow the instructions given in *Replacing electrodes* on page E-32.

- After replacing an electrode, the **Electrode Service** maintenance action needs to be performed. This action will be performed as part of the maintenance procedure of the **Prepare** wizard.
- After replacing an electrode, a main calibration needs to be performed. This action will be performed as part of the **Daily Prepare Actions** maintenance action.

■

Replacing ISE fluid bottles

A bottle with a blue label for ISE Calibrator indirect/urine and a bottle with a red label for ISE Reference Solution are located on the ISE unit. The procedure for exchanging these bottles is the same.

► To replace an on-board ISE fluid bottle

1 Follow the instructions given in *Replacing ISE fluid bottles* on page E-30.

- After replacing an ISE fluid bottle, the **Prime ISE Reference and Calib.** maintenance action needs to be performed. This action will be performed as part of the maintenance procedure of the **Prepare** wizard.
- After replacing an ISE fluid bottle, a main calibration needs to be performed. This action will be performed as part of the **Daily Prepare Actions**.

2 When you have finished replacing electrodes and ISE fluid bottles, press [»] to proceed to the next stage in the **Prepare** wizard.

A screen is displayed that lists the maintenance actions.

■

Performing maintenance actions

The routine maintenance actions that are relevant for working with the ISE unit are integrated in one single maintenance action: **Daily Prepare Actions**.

For general information on performing maintenance actions, see *Performing maintenance actions* on page B-19.
For details on how to perform individual ISE maintenance actions, see *ISE maintenance actions* on page E-42.

► To perform maintenance actions

1 Select **Daily Prepare Actions**.

2 Press [▶].

The maintenance definition screen is displayed.

3 Follow the instructions given on the screen.

See *Daily prepare actions* on page E-44.

4 Perform the non-routine ISE maintenance actions.

Follow the instructions given on the screen.

■

When performing maintenance actions without using the Prepare wizard:

Choose **Utilities** > **Maintenance**.

Completing the preparation tasks

1 When you have finished performing maintenance actions, press [»] to proceed to the next stage in the **Prepare** wizard.

A screen is displayed that shows the status of the reagents on the reagent disk. This is not relevant for ISE operation.

2 Press [»].

A screen is displayed that shows the status of the cuvettes that are on board. This is not relevant for ISE operation.

3 Press [»].

A screen is displayed that shows the tests that need calibrating. Because the calibrations have already been performed as part of the **Daily Prepare Actions** maintenance action, this step is not relevant for ISE operation.

4 Press [»].

The **Overview** tab is displayed. The preparation tasks are completed.

Performing calibrations

The ISE calibrations are integrated in the **Daily Prepare Actions** maintenance action.

See *Daily prepare actions* on page E-44.

Defining orders

ISE sample analysis is integrated in the operation of the main instrument. The process of defining orders is the same.

► To define orders

1 Follow the instructions given in *Defining orders* on page B-38.

ISE tests are defined and requested as profiles. (There is hardly ever the need for electrolytic measurements of just one electrode.)

■

Monitoring the progress

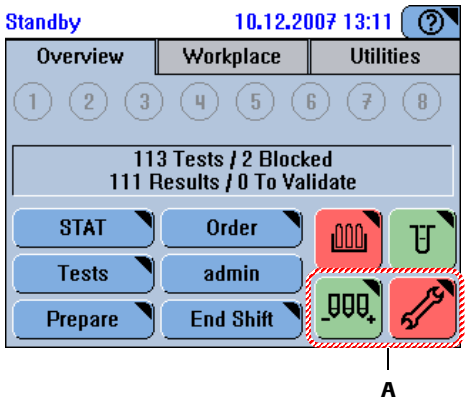
► To monitor the progress

1 Follow the instructions given in *Monitoring the analysis progress* on page B-44.

■

► To check the instrument status

1 Press the **Overview** tab.



A Relevant instrument status buttons

Figure E-4

Interpreting the instrument status buttons

Icon		Meaning	Possible action
		The ISE unit is in standby.	No action is required.
		The expiration date of an electrode has passed or an on-board ISE fluid level is low.	1. Check the details on the dedicated **System Status** screen. 2. Replace the electrode or ISE fluid bottle as soon as possible.
		The ISE unit is blocked.	1. Check the details on the dedicated ISE status screen. 2. Act accordingly.

Icon	Meaning	Possible action
System Status	The **System Status** button displays both the icon and the color of one of the buttons of the underlying **System Status** screen. (The icons are first prioritized by color, first priority being red, followed by yellow and green, and then according to the sequence in which they are listed below.)	
	Analyzer (main cover)	Press the button and on the **System Status** screen check the text about the status of the main cover.
	Reagent cooler and cuvette ring temperature	Press the button and on the **System Status** screen check the text about the temperature.
	Sample area ventilation	Press the button and on the System Status screen check the text about the ventilation status.
	External fluid containers	Press the button and on the **System Status** press it again to display the screen for handling the external fluid containers.
	Maintenance	Press the button and on the **System Status** press it again to display the maintenance actions list.
	Printer	Press the button and on the **System Status** screen check the text about the printer status.

■

Acoustic signal An acoustic signal informs you of the fact that all tests are finished and the system status has changed to **Standby**.

Validating sample results

ISE result handling is integrated in the operation of the main instrument. The process of reviewing results is the same.

► To validate sample results

1 Follow the instructions given in *Validating sample results* on page B-51.

👁 For information on ISE flags, see *List of ISE flags* on page E-71.

■

Main calibration

The main calibration of the electrodes must be performed periodically. It also needs to be performed after certain maintenance actions.

For the indirect method, the sodium (NA-I), potassium (K-I), and chloride (CL-I) tests are calibrated with a two-point calibration using ISE Solution 1 and 2.

For urine, the sodium (NA-U), potassium (K-U), and chloride (CL-U) tests are calibrated with a two-point calibration using ISE Solution 1 and 2.

The main calibration is typically performed during the **Prepare** phase and, if there follows a second shift, at the end of a shift. It is integrated in the **Daily Prepare Actions** maintenance action.

For details on performing the **Daily Prepare Actions** maintenance action, see *Daily prepare actions* on page E-44.
For details on performing individual calibrations, see *Process of performing calibrations* on page B-61.

Performing QC

ISE QC handling is integrated in the operation of the main instrument.

► To perform QC

Follow the instructions given in *Performing QC* on page B-68.

■

Finishing the shift

ISE Standby status

If there is no measurement for more than three minutes, the ISE unit switches to Standby status. In this status, ISE Calibrator indirect/urine and ISE Reference Solution are pumped into the measuring channel and moved a short distance at regular intervals. Also, every two hours, the ISE tubing is primed with ISE Calibrator indirect/urine and ISE Reference Solution. This is done to prevent the following:

- Flow of ISE Reference Solution backwards into the measuring channel, which can damage the electrodes because of the high ion concentration of the ISE Reference Solution.
- Crystallization of salts in the tubing, which can cause blockages.

The ISE unit has a separate power supply. Therefore, the Standby status is maintained even if the main instrument is switched off.

NOTICE

Damage to electrodes and possible tubing blockage

Do not unplug or switch off the ISE power supply. Periodic flow of solutions must be performed at all times.

End Shift wizard

The end of shift activities are organized in a single wizard. By performing the steps as suggested by this wizard, you put the system in a condition that allows you to hand over operation to another operator or to switch off the instrument.

The following table provides an overview on the steps that make up the end of shift process.

For details on performing the individual tasks, see the instructions in *Finishing the shift* on page B-77.

Short guide

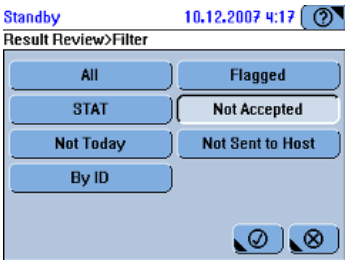
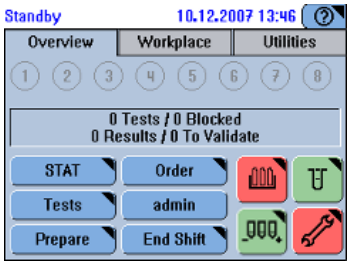
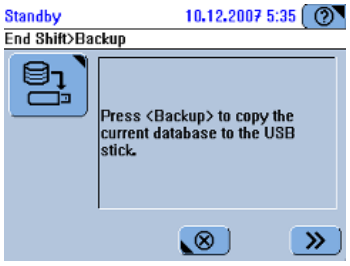
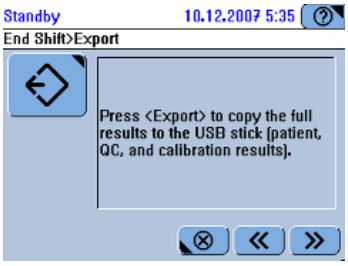
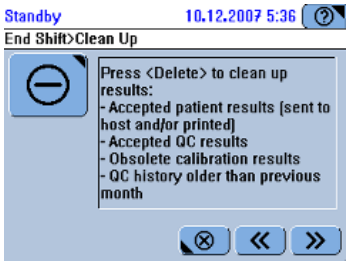
Step		User action
1	Check for unfinished tasks. 	1. Check for unfinished orders. 2. Check for nonvalidated results. 3. Check for results that were not transmitted.
2	Start the **End Shift** wizard. 	1. On the **Overview** tab, press the **End Shift** button.
3	Perform data backup. 	1. Press . 2. Insert the USB stick. 3. Press . 4. Select the directory. 5. Press . 6. Press to proceed to the next stage in the **End Shift** wizard.
4	Export support data. 	1. Press . 2. Insert the USB stick, if you have removed it. 3. Press . 4. Select the directory. 5. Press . 6. Remove the USB stick. 7. Press to proceed to the next stage in the **End Shift** wizard.
5	Clean up the database. 	1. Press . 2. Press to confirm the deletion. 3. Press to proceed to the next stage in the **End Shift** wizard.

Table E-5 Steps for finishing the shift

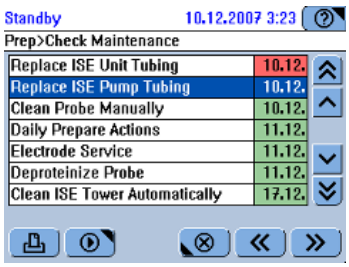
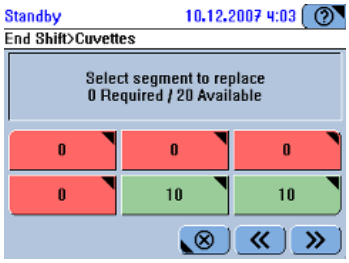
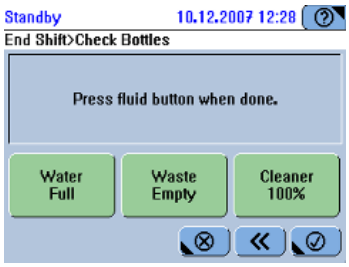
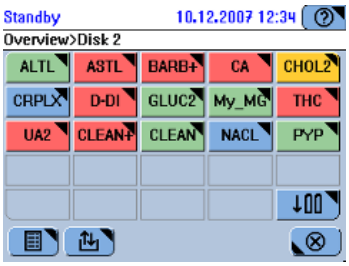
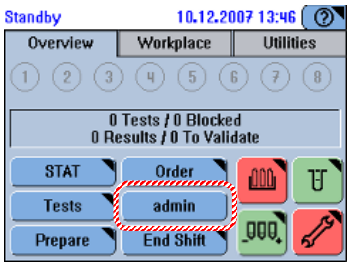
Step		User action
6	Perform maintenance actions. 	1. Check which maintenance actions are due. 2. Perform the maintenance actions. Perform at least all red maintenance actions. 3. Press [»] to proceed to the next stage in the **End Shift** wizard.
7	Check the cuvette status. (Not relevant for ISE operation.) 	1. Press [»] to proceed to the next stage in the **End Shift** wizard.
8	Empty the waste container. 	1. Empty the waste container. 2. Press the **Waste** button to confirm. 3. Refill the water container. 4. Press the **Water** button to confirm.
9	Remove the reagent disk. (Not relevant for ISE operation.) 	
10	Finish your shift. 	1. Log off the system. 2. Switch off the main instrument. (If there is no other shift.)

Table E-5 Steps for finishing the shift

If you intend not to use the ISE unit for more than one week, you should deactivate it. This saves ISE fluids and reduces wear and tear of the tubing. (See *Deactivating the ISE unit* on page E-64.)

Replacing ISE fluid bottles

ISE fluid bottles are supplied with a barcode that contains information on their expiration date, which is monitored by the system.

Roche recommend replacing ISE fluid bottles as soon as their expiration date has passed. (Their icon on the screen turns yellow.)

For information on the stability of fluids, see their package inserts.

Tools and materials required

- ISE Calibrator indirect/urine or ISE Reference Solution bottle
- Tissues

WARNING

Injury through working solutions

Direct contact with cleaning solutions or other working solutions may cause personal injury.

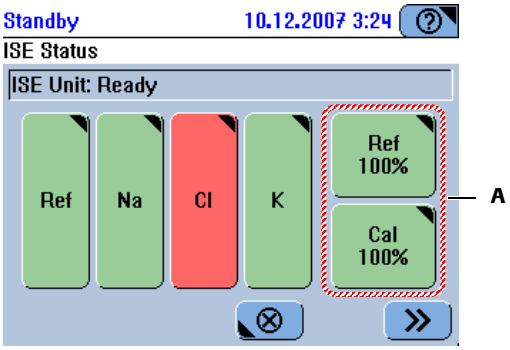
When handling such solutions, exercise the precautions required for handling them, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics cleaning solutions.

► To replace an on-board ISE fluid bottle

1 Check that the system is in **Standby** status.

2 Choose **Overview** > .

3 Check the status of the ISE bottles (A).



Interpreting the bottle status screen

	No fluid registered by an ISE fluid sensor. (Operation has stopped.) You need to replace the bottle now.
	The fluid level in the bottle is low. (Operation will proceed until one of the sensors detects that there is no fluid.) The fluid's expiration date has passed. You should replace the bottle as soon as possible.
	No action is required.

4 Press **Cal** or **Ref**.

A screen is displayed that shows details about the bottle status.

5 Press .

A screen is displayed, asking you to scan the bottle barcode or to type it manually.

6 Scan the bottle barcode.

7 Press .

8 Observe the messages on screen and react accordingly.

If the barcode cannot be read, type it manually.

When the scanning process is finished, a message is displayed, asking you to replace the bottle.

9 Open the ISE cover.

10 Remove the tubing adapter by lifting it and placing it on a clean lint-free tissue.

11 Remove the bottle.

12 Remove the cap of the new bottle.

13 Place the new bottle.

Make sure to place a full bottle.

14 Insert the tubing adapter.

15 Close the ISE cover.

16 On the screen, press to confirm the placement.

The system performs the **Prime ISE Reference and Calib.** maintenance action.

17 Press to close the screen for reading barcodes.

You need to perform a main calibration before you can process orders.

18 On the ISE status screen, press .

A placement list is displayed, telling you where to place ISE Solution 1 and 2.

19 Place ISE Solution 1 and ISE Solution 2 on the positions indicated on the screen.

20 Press .

The **Overview** tab is displayed.

21 Press to perform the main calibration.

22 When the system is in **Standby** status, remove ISE Solution 1, and ISE Solution 2 from the sample area.

23 Press .

■

Replacing electrodes

Roche recommend replacing electrodes when their expiration date is reached.

For information on the stability of the electrodes, see their package inserts.

There are up to three ion-selective electrodes and one ISE Reference Electrode on the ISE unit. The replacement procedure is the same for all of them.

As part of replacing electrodes, the **Electrode Service** maintenance action and a main calibration need to be performed.

Replacing an electrode takes about 15 minutes.

Tools and materials required

- ISE Calibrator indirect/urine (on board)
- ISE Reference Solution (on board)
- ISE Deproteinizer
- ISE Etcher
- Activator
- ISE Solution 1
- ISE Solution 2
- ISE Sodium Electrode (if you intend to replace this type of electrode)
- ISE Potassium Electrode (if you intend to replace this type of electrode)
- ISE Chloride Electrode (if you intend to replace this type of electrode)
- ISE Reference Electrode (if you intend to replace this type of electrode)
- ISE Dummy Electrode (if you intend to replace this type of electrode or if you no longer intend to use one of the ion-selective electrodes)

Make sure that you have read and understood section *Safety information* on page E-19. The following warning messages in particular are relevant:

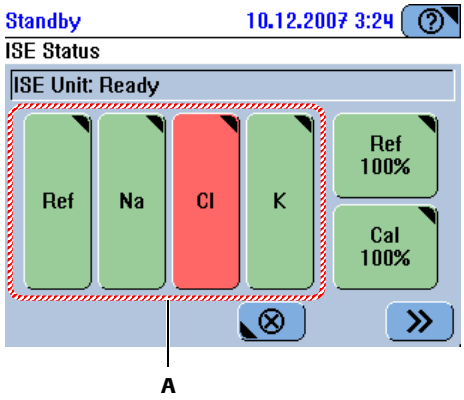
- *Injury through reagents and other working solutions* on page E-19.
- *Injury through reagents and other working solutions* on page E-19.

► To replace an electrode

1 Check that the system is in **Standby** status.

2 Choose **Overview** > .

The ISE status is displayed.



A Electrode buttons

Figure E-5

3 Press the button of the electrode you want to replace.

Details of the electrode status are displayed.

4 Press to start the exchange wizard.

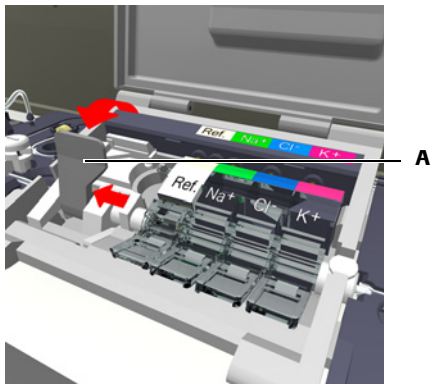
The system rinses the electrodes with ISE Calibrator indirect/urine to remove any sample residue and then drains all electrodes.

You are asked to remove the electrode. (Make sure to remove the electrode that is marked on the screen.)

5 Open the ISE cover.

6 Open the electrode block lid.

7 Release the tension lever (A).



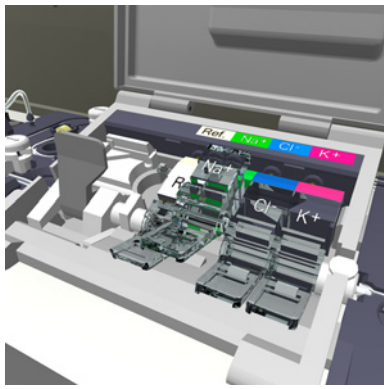
A Tension lever

Figure E-6

Turning the tension lever releases the electrodes. You may have to push the anchoring piece towards the tension lever to create enough space for removing the electrodes.

8 Remove the electrode.

Lift it at the front to disengage, then remove it.



9 On the screen, press the electrode button to confirm that you have removed the electrode.

You are asked to scan the barcode of the new electrode or to type its ID manually.

10 Scan the electrode barcode on the package insert or type the ID manually.

(If you want to install a dummy electrode scan its barcode.)

You are asked to insert the new electrode.

Fixed electrode positions

Always replace an electrode with the same type or with an ISE Dummy Electrode. (The ISE Reference Electrode must always be replaced with another ISE Reference Electrode. ISE Dummy Electrode is not allowed on this position.)

Keeping the barcode

Keep the electrode barcode in a safe place. You will need it again in the case of a database import.

11 Insert the new electrode.

Push it back towards the contacts and press it down until it clicks into place.

12 Fasten the tension lever.

13 Close the electrode block lid.

14 On the screen, press the electrode button to confirm that you inserted the electrode.

(If you inserted a dummy electrode, press the button of the electrode you replaced with a dummy electrode.)

A screen is displayed that shows detailed information on the electrode.

15 Press ⊗.

At this stage, if you want to replace another electrode, press its button and continue with step 7.

16 Close the ISE cover.

17 On the ISE status screen, press » to continue the process.

A placement list is displayed.

18 Place the Activator, ISE Deproteinizer, ISE Etcher, ISE Solution 1, and ISE Solution 2 on the sample area positions indicated on the screen.

19 Press ✓ to confirm the placement and to start the action.

The system performs the **Electrode Service** maintenance action.

20 Press ◇ to perform the main calibration.

A message will inform you when the action is complete.

21 When the system is in **Standby** status, remove the Activator, ISE Deproteinizer, ISE Etcher, ISE Solution 1, and ISE Solution 2 from the sample area.

22 Press ⊗.

■

Cleaning the ISE tower off the instrument

If performing the **Clean ISE Tower Manually** maintenance action did not lead to the desired results, you need to remove the ISE tower to clean it.

Cleaning the ISE tower off the instrument consists of the following steps:

1. Removing the ISE tower
2. Soaking the ISE tower in ISE Deproteinizer
3. Cleaning and drying the ISE tower
4. Installing the ISE tower
5. Performing the maintenance action **Clean ISE Tower Automatically**.

Tools and materials required

- Cotton swabs
- ISE Deproteinizer
- Small glass beaker

Make sure that you have read and understood section *Safety information* on page E-19. The following warning messages in particular are relevant:

- *Infection by biohazardous materials* on page E-19.
- *Injury through reagents and other working solutions* on page E-19.

► To clean the ISE tower

Removing the ISE tower

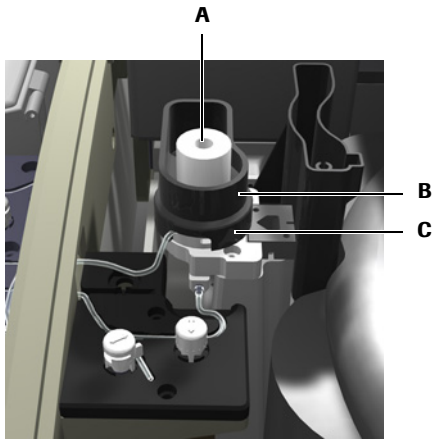
1 Make sure the system is in **Standby** status.

2 Switch off the instrument.

3 Move the transfer head to its rightmost position.

4 Open the main cover and the left service flap.

5 Remove the ISE overflow collector by pulling it upwards and turning it from side to side as you do so.



A ISE tower
B ISE overflow collector
C Locking ring

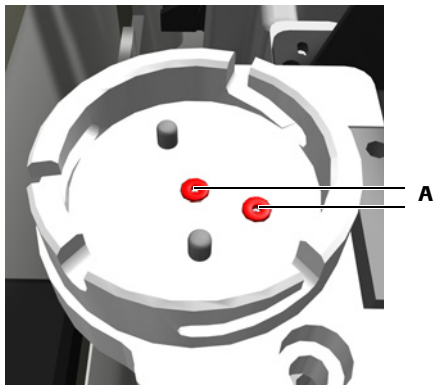
Figure E-7

Place the collector behind the wash station.

6 Remove the locking ring from the base of the ISE tower by turning it counter-clockwise one quarter of a turn and then lifting it over the ISE tower.

7 Lift the ISE tower and carefully disconnect the tubing.

Check whether any O-ring is stuck to the ISE tower. If so, remove it and place it back in its position on the ISE tower base.



A O-ring positions

Figure E-8

Cleaning the ISE tower

8 Clean the inside of the ISE tower with a cotton swab to remove any visible clots.

9 Pour ISE Deproteinizer in the beaker.

10 Soak the ISE tower in the ISE Deproteinizer for about 5 minutes.

(If there are clots in the tower, you can extend the soaking time to 30 minutes.)

11 Rinse the ISE tower with deionized water and leave it to dry.

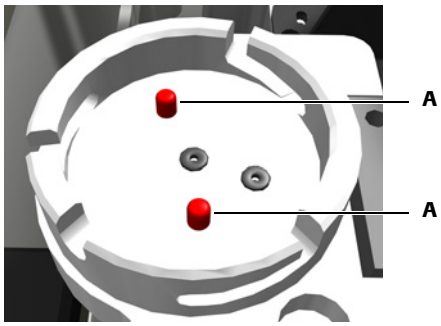
Reinstalling the ISE tower

12 Reconnect the tubing to the ISE tower.

13 Make sure that both O-rings are present and seated on the tower base.

14 Place the ISE tower on its base.

Align the two pins on the base with the two holes in the ISE tower.



A Alignment pins

Figure E-9

15 Reinstall the locking ring.

Make sure it is properly engaged and turn it firmly clockwise.

16 Reinstall the overflow collector.

17 Close the left service flap and the main cover.

Finishing the task

18 Switch on the instrument.

19 Wait for initialization to finish.

20 Log on to the system.

21 Perform the maintenance action **Clean ISE Tower Automatically**.

See *Clean ISE tower automatically* on page E-50.

■

ISE maintenance

In this chapter, you will find step-by-step instructions of the ISE-specific maintenance actions that you must perform to keep the instrument running smoothly and efficiently.

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Introduction

The maintenance actions of the ISE unit are integrated in the maintenance actions of the main instrument.

For general information on performing maintenance actions, see *Overview* on page C-5.

This chapter describes the ISE-specific maintenance actions.

ISE maintenance actions and their intervals

The following table lists the ISE maintenance actions and shows how frequently they need to be performed.

Every effort has been made to ensure that all the information contained in this table is correct at the time of publication. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.

Maintenance actions with no defined interval need to be performed in particular situations, for example during troubleshooting.

Interval	Maintenance action
None (Initiated by other maintenance action)	**Activate Electrodes**
None (Initiated by other maintenance action)	**Condition ISE Tubing**
None (Initiated by other maintenance action)	**Initialize ISE Reference Sensor**
None (Initiated by other maintenance action)	**Prime ISE Reference and Calib.**
Daily	**Daily Prepare Actions**
Daily	**Electrode Service**
Weekly	**Clean ISE Tower Automatically**
Monthly	**Clean ISE Tower Manually**
Monthly	**Initialize ISE Unit**
Six-monthly	**Replace ISE Unit Tubing**
Six-monthly	**Replace ISE Pump Tubing**

Table E-6 Periodicity of maintenance actions

For the expiration dates of electrodes, see their package inserts.

ISE maintenance actions

Safety information

WARNING

Injury through working solutions

Direct contact with cleaning solutions or other working solutions may cause personal injury. When handling such solutions, exercise the precautions required for handling them, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics cleaning solutions.

Personal injury or damage to the analyzer due to contact with instrument mechanism

Do not touch moving parts during instrument operation.

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Incorrect results due to build-up of contaminants

During use, contaminants may adhere to the probe. As a result, traces of analytes or reagents may be carried over to the next. Make sure to perform the probe maintenance actions as soon as they are due in order to prevent potentially false results.

Incorrect results or damage to the analyzer due to dust and soiling

The user can leave the main cover open while the system is in **Standby** status or while the instrument is shut down. This can cause dust and dirt being collected in the heating channel, which in turn might decrease the quality of the cuvettes.

Keep all covers closed. Open them only to perform operation actions.

Incorrect results or processing stop due to skipping maintenance actions

Not performing maintenance actions that are due may lead to situations where the system cannot continue processing orders, or it may lead to incorrect results. If at all possible, perform the maintenance actions when they are due.

Incorrect results or processing stop due to incomplete maintenance actions

You can cancel a maintenance action any time by pressing ⊗.

If you interrupt the performing of a maintenance action that was due, its status will remain due, and you need to fully re-perform the action later.

If at all possible, complete a maintenance action without interrupting it.

WARNING

Incorrect results or damage to the analyzer due to wrong operation

Operators are required to have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Start all maintenance actions on the screen. Do not perform maintenance actions without the assistance of the user interface.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to a trained service representative.
- Follow standard laboratory practices, especially when working with biohazard material.

Danger of poor measurement quality due to inadequate water quality

Inadequate water quality may lead to incorrect results. Always use purified water of the quality specified in section *Technical specifications*.

Infection by waste solution

Contact with waste solution may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Whenever the term "purified water" is used in this document, water of at least the quality specified in chapter *Technical specifications* must be used.

Daily prepare actions

➔ **Utilities > Maintenance > Daily Prepare Actions**

To make it easier and more efficient for the operator, some daily maintenance actions that may take quite some time are grouped into one maintenance action. This way the operator does not have to remain near the instrument while the actions are performed.

The following maintenance actions are included if due:

- **Initialize ISE Unit**
- **Electrode Service**
- **Clean ISE Tower Automatically**
- **Deproteinize Probe**

In addition, a main calibration is performed.

Operator time Approximately 25 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required

- ☐ ISE Deproteinizer
- ☐ Activator
- ☐ ISE Etcher
- ☐ ISE Solution 1
- ☐ ISE Solution 2

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Incorrect results due to build-up of contaminants* on page E-42.

► To perform the daily prepare actions

1. Prepare a tube with ISE Deproteinizer, ISE Etcher, Activator, ISE Solution 1, and ISE Solution 2 each.
2. Select the maintenance action **Daily Prepare Actions**.
3. Press ⓞ.

   The maintenance definition screen is displayed.
4. Press ⓥ.

   A placement list is displayed.
5. Place the fluids on the positions indicated on the screen.
6. Press ⓥ to confirm the placing.

   The system performs the maintenance actions.
7. When the system is in **Standby** status, remove the tubes.
8. Press ⓧ.

■

Activate electrodes

➔ **Utilities** > **Maintenance** > **Activate Electrodes**

The electrode surfaces must be activated with fresh serum so that the correct potentials are measured. Electrodes may be damaged if they are deprived of regular contact with serum.

Operator time Approximately 4 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required ☐ Activator

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42.

► To activate the electrodes

1. Select the maintenance action **Activate Electrodes**.
2. Press ⓞ.

   The maintenance definition screen is displayed.
3. Press ⓥ to start the action.

   A placement list is displayed.
4. Place the Activator on the sample area position indicated on the screen.
5. Press ⓥ to confirm the placement and to start the action.

   A message will inform you when the maintenance action is complete.
6. Remove the Activator from the sample area.
7. Press ⓧ.

■

Condition ISE tubing

➔ **Utilities** > **Maintenance** > **Condition ISE Tubing**

Conditioning the tubing with Activator ensures the proper flow of fluids.

Operator time Approximately 3 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required ☐ Activator

Make sure that you have read and understood section *Safety information* on page E-42.
The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42.

► To condition the ISE tubing

1. Select the maintenance action **Condition ISE Tubing**.
2. Press ⓞ.
   The maintenance definition screen is displayed.
3. Press ⓥ to start the action.
   A placement list is displayed.
4. Place the Activator on the sample area position indicated on the screen.
5. Press ⓥ to confirm the placement and to start the action.
   A message will inform you when the maintenance action is complete.
6. Remove the Activator from the sample area.
7. Press ⓧ.

■

Initialize ISE Reference Solution sensor

➔ **Utilities > Maintenance > Initialize ISE Reference Sensor**

Initializing the ISE Reference Solution sensor ensures proper detection of possible air in the ISE tubing.

This maintenance action forms part of the **Replace ISE Unit Tubing** maintenance action.

Operator time Approximately 1 minute.

Prerequisites The system must be in **Standby** status.

Tools and materials required ☐ Tissues

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42.

► To initialize the ISE Reference Solution sensor

1 Select the maintenance action **Initialize ISE Reference Sensor**.

2 Press ⓞ.

The maintenance definition screen is displayed.

3 Press ⓥ to start the action.

The instrument pumps ISE Reference Solution through the ISE tubing.

You are asked to remove the tubing adapter from the ISE Reference Solution bottle.

4 Open the ISE cover.

5 Remove the tubing adapter from of the ISE Reference Solution bottle.

- Have a clean lint-free tissue ready.
- Lift the tubing adapter and place it on the tissue.

6 Press ⓥ to confirm completion of the action.

The system now starts to initialize the ISE Reference Solution sensor.

You are asked to insert the tubing adapter in the ISE Reference Solution bottle and to close the ISE cover.

7 Insert the tubing adapter in the ISE Reference Solution bottle.

8 Close the ISE cover.

9 Press ⓥ.

The instrument pumps ISE Reference Solution through the ISE tubing.

A message will inform you when the maintenance action is complete.

10 Press ⓧ.

■

Prime ISE reference and calibrator

➔ **Utilities** > **Maintenance** > **Prime ISE Reference and Calib.**

This maintenance action ensures that no traces of a previous ISE Calibrator indirect/urine and ISE Reference Solution are left in the tubing and so prevents drift in the results.

Operator time Approximately 1 minute.

Prerequisites The system must be in **Standby** status.

Tools and materials required None

Hazards and precautions None

► **To prime the ISE calibrator and ISE Reference Solution**

1 Select the maintenance action **Prime ISE Reference and Calib.**

2 Press ⓞ.

The maintenance definition screen is displayed.

3 Press ⓥ to start the action.

The instrument pumps first ISE Reference Solution and then ISE Calibrator indirect/urine through the ISE tubing and past the electrodes.

A message will inform you when the maintenance action is complete.

4 Press ⓧ.

■

Electrode service

➔ **Utilities** > **Maintenance** > **Electrode Service**

The electrodes must be cleaned regularly to prevent the buildup of deposits and so to maintain the efficiency of the ISE unit.

During this action, the ISE Sodium Electrode is etched and all electrodes are deproteinized and activated, and the tubing is conditioned.

Operator time Approximately 9 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required

- ☐ ISE Etcher
- ☐ Activator
- ☐ ISE Deproteinizer

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42.

► To perform electrode service

1. Select the maintenance action **Electrode Service**.
2. Press ⓞ.

   The maintenance definition screen is displayed.
3. Press ⓥ to start the action.

   A placement list is displayed.
4. Place the Activator, ISE Deproteinizer, and ISE Etcher on the sample area positions indicated on the screen.
5. Press ⓥ to confirm the placement and to start the action.

   A message will inform you when the maintenance action is complete.
6. Remove the Activator, ISE Deproteinizer, and ISE Etcher from the sample area.
7. Press ⓧ.

■

You need to perform a main calibration before you can process orders.

Clean ISE tower automatically

➔ **Utilities > Maintenance > Clean ISE Tower Automatically**

The ISE tower must be cleaned regularly to ensure the proper functioning of the ISE unit. Cleaning includes deproteinizing and activating the ISE tower.

Operator time Approximately 3 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required
- ☐ Activator
- ☐ ISE Deproteinizer

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42.

► To clean the ISE tower automatically

1. Select the maintenance action **Clean ISE Tower Automatically**.
2. Press ⓞ.

   The maintenance definition screen is displayed.
3. Press ⓥ to start the action.

   A placement list is displayed.
4. Place the Activator and the ISE Deproteinizer on the sample area positions indicated on the screen.
5. Press ⓥ to confirm the placement and to start the action.

   A message will inform you when the maintenance action is complete.
6. Remove the Activator and ISE Deproteinizer from the sample area.
7. Press ⓧ.

■

Clean ISE tower manually

➔ **Utilities > Maintenance > Clean ISE Tower Manually**

When the ISE tower is blocked, perform first the **Clean ISE Tower Automatically** maintenance action (See *Clean ISE tower automatically* on page E-50). If this does not help, perform the **Clean ISE Tower Manually** maintenance action. If the ISE tower is still blocked, clean the ISE tower off the instrument. (See *Cleaning the ISE tower off the instrument* on page E-36.)

Operator time Approximately 6 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required

- ☐ ISE Deproteinizer
- ☐ Activator
- ☐ Cotton swabs

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42.

► To clean the ISE tower

1 Select the maintenance action **Clean ISE Tower Manually**.

2 Press ⓞ.

The maintenance definition screen is displayed.

3 Press ⓥ to start the action.

A placement list is displayed.

4 Place the Activator and ISE Deproteinizer on the sample area positions indicated on the screen.

5 Press ⓥ to confirm the placement and to start the action.

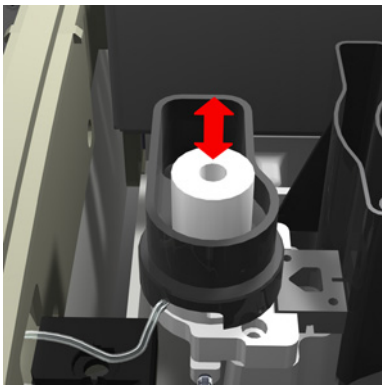
The ISE tower is first washed.

The transfer head moves to the right side of the instrument.

You are asked to clean the ISE tower.

6 Open the main cover and then the left service flap.

7 Clean the inside of the ISE tower with a cotton swab to remove any residual of ISE Deproteinizer.



8 Close the left service flap and then the main cover.

9 Press ⊘ to confirm the cleaning of the ISE tower.

The ISE tower is first washed.

The transfer head moves to the right side of the instrument.

You are asked to clean the ISE tower.

10 Open the main cover and then the left service flap.

11 Clean the inside of the ISE tower with a cotton swab to remove any residual water.

12 Close the left service flap and then the main cover.

13 Press ⊘ to confirm the cleaning of the ISE tower.

The ISE tower is first washed and dried and then conditioned with Activator.

A message will inform you when the maintenance action is complete.

14 Remove the Activator and ISE Deproteinizer from the sample area.

15 Press ⊗.

■

Initialize ISE unit

➔ **Utilities** > **Maintenance** > **Initialize ISE Unit**

Initializing the ISE unit uses Activator to condition the electrodes and to adjust the sensors and the pump action. This ensures proper transportation of fluids through the ISE tubing.

Operator time Approximately 3 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required ☐ Activator

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Infection by biohazardous materials* on page E-42.

► To initialize the ISE unit

1. Select the maintenance action **Initialize ISE Unit**.
2. Press ⓞ.

   The maintenance definition screen is displayed.
3. Press ⓥ to start the action.

   A placement list is displayed.
4. Place the Activator on the sample area positions indicated on the screen.
5. Press ⓥ to confirm the placement and to start the action.

   A message will inform you when the maintenance action is complete.
6. Remove the Activator from the sample area.
7. Press ⓧ.

■

Replace ISE pump tubing

➔ **Utilities** > **Maintenance** > **Replace ISE Pump Tubing**

Replacing the pump tubing ensures proper ISE pump action.

During the **Replace ISE Pump Tubing** maintenance action, the following maintenance actions are automatically performed:

- **Prime ISE Reference and Calib.**
- **Initialize ISE Unit**

Operator time Approximately 10 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required

- ☐ Activator
- ☐ Roche approved ISE pump tubing set

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42.
- *Infection by waste solution* on page E-43.

► To replace the ISE pump tubing

1. Select the maintenance action **Replace ISE Pump Tubing**.
2. Press ⏵.

   The maintenance definition screen is displayed.
3. Press ✓ to start the action.

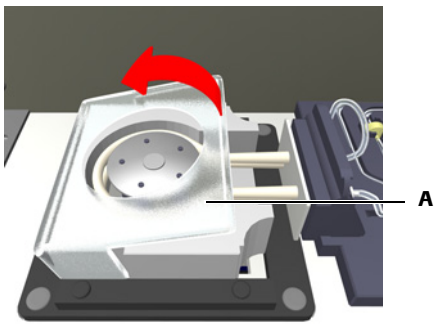
   The placement screen is displayed.
4. Place the Activator on the sample area position indicated on the screen.
5. Press ✓ to confirm the placement.

   The tubing is emptied.

   Your are asked to remove the tubing.
6. Open the ISE cover.

Removing the tubing

7 Open the cover of the peristaltic pump.

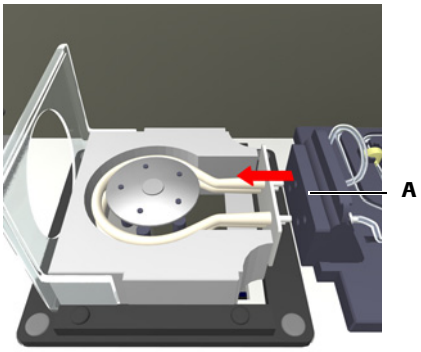


A Cover of peristaltic pump

Figure E-10

8 Push the pump towards the back of the instrument.

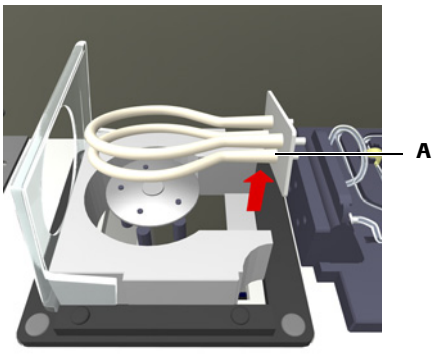
9 Disengage the tube connector plate.



A Connector plate

Figure E-11

10 Remove the ISE pump tubing set.



A ISE pump tubing set

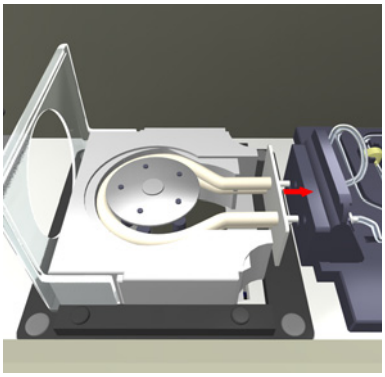
Figure E-12

Installing the tubing

Install the tubing in the reverse order of removing it.

11 Pull the new tubing set over the pump head, with the connector plate facing the electrode block.

12 Align the tubing connector plate with the tube connectors on the ISE unit.



13 Carefully close the peristaltic pump lid.

The tube connector plate is automatically pushed into the tube connectors of the ISE unit.

14 Close the ISE cover.

15 Press ✓ to confirm completion of the action.

The system first performs the **Prime ISE Reference and Calib.** maintenance action, then **Initialize ISE Unit**.

A message will inform you when the maintenance actions are complete.

16 Remove the Activator from the sample area.

17 Press ⊗.

■

Replace ISE unit tubing

➔ **Utilities > Maintenance > Replace ISE Unit Tubing**

Due to the abrasion by the ISE valve action, the ISE tubing needs to be replaced periodically. Replacing the ISE tubing ensures the proper functioning of the ISE unit.

During the **Replace ISE Unit Tubing** maintenance action, the following maintenance actions are automatically performed:

- **Prime ISE Reference and Calib.**
- **Initialize ISE Reference Sensor**
- **Condition ISE Tubing**
- **Initialize ISE Unit**

Always replace the ISE tubing with the help of the **Replace ISE Unit Tubing** maintenance action.

Operator time Approximately 15 minutes.

Prerequisites The system must be in **Standby** status.

Tools and materials required

- ☐ Activator
- ☐ Roche approved ISE unit tubing set
- ☐ Tissues

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning messages in particular are relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42.
- *Infection by waste solution* on page E-43.
- *Personal injury or damage to the analyzer due to contact with instrument mechanism* on page E-42.

► To remove the ISE unit tubing

1. Select the maintenance action **Replace ISE Unit Tubing**.
2. Press ⏵.

   The maintenance definition screen is displayed.
3. Press ✓ to start the action.

   The placement screen is displayed.
4. Place the Activator on the sample area position indicated on the screen.
5. Press ✓ to confirm the placement.

   The tubing is emptied.

   Your are asked to open the covers.
6. Open the main cover, then the left service flap and the ISE cover.

   Your are asked to remove the tubing adapters from the ISE solution bottles.

Disconnecting the ISE solution bottles

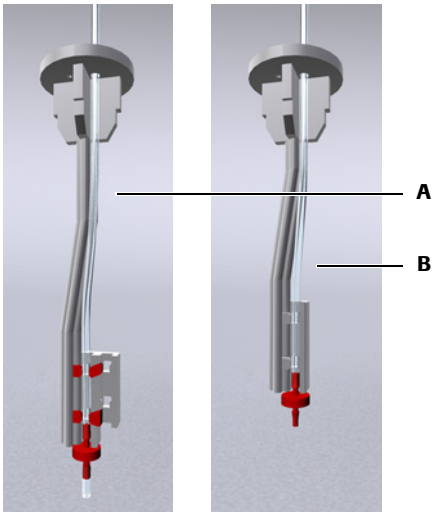
7 Remove the tubing adapters from ISE Calibrator indirect/urine and ISE Reference Solution bottles.

8 Press ✓ to confirm the removal.

The tubing is drained.

9 Remove the tubing from the adapters.

The two tubing adapters are slightly different, but the process of removing the tube is the same.



A ISE Reference Solution tubing adapter **B** ISE Calibrator indirect/urine tubing adapter

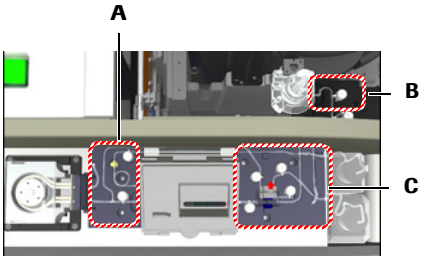
Figure E-13

- Have a tissue ready.
- Remove the tubing adapter by lifting it and place it on the clean lint-free tissue.
- Remove the tube from its clips.
- Remove the nozzle from the tube by pulling it off.
- Pull through the tube from the top of the adapter.

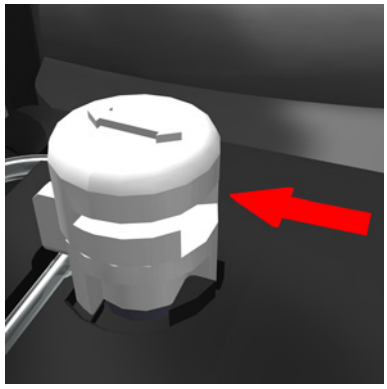
  Place the adapter together with its nozzle on the tissue.

Removing the pinch valve caps and clamps

10 Remove the pinch valve caps and clamps of the input (B), entry (C), and exit (A) valve-plates.



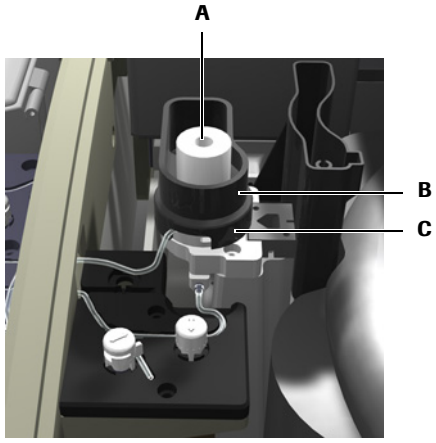
To remove a pinch valve cap and clamp:



- Push the cap horizontally in the direction of the arrow, away from the cut-out.
- Lift and put it aside.
- Lift the valve clamp and put it aside.

Disconnecting the tubing from ISE tower

11 Disconnect the tubing from the ISE tower

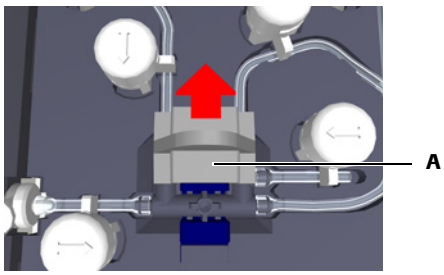


- Remove the ISE overflow collector (B) by pulling it upwards and turning it from side to side as you do so.

  Place the collector behind the wash station.
- Remove the locking ring (C) from the base of the ISE tower by turning it counter-clockwise one quarter of a turn and then lifting it over the ISE tower.
- Lift the ISE tower (A). Check whether any O-ring is stuck to the ISE tower. If so, remove it and place it back in its position on the ISE tower base.
- Disconnect the tubing.

Do not remove the piece of tubing at the underside of the mixing tower. It will be changed when a service representative performs periodic maintenance.

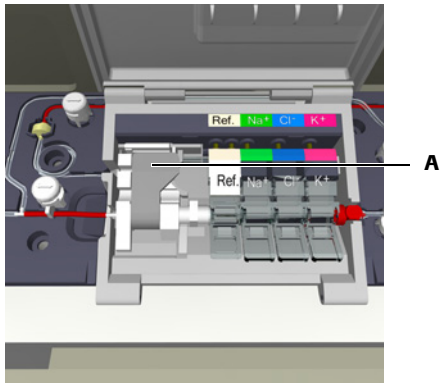
12 Slide off the lid of the fluid distributor.



A Lid of fluid distributor

Figure E-14

13 Disconnect the tubing from the electrode block.



A Tension lever

Figure E-15

- Open the electrode block lid.
- Release the tension lever.
- Lift the connector on the side of the K electrode.
- Disconnect the tube on the side of the tension lever.
- Lift the connector to the ISE Reference Electrode and disconnect the tube leading to the ISE Reference Solution bottle.

14 Disconnect the tubing connecting to the peristaltic pump.

Removing the tubing

15 Lift the tubing from its routing, follow carefully the individual tubes.

16 Dispose of the tubing. Treat it as biohazardous waste.

Installing the new tubing

17 Install and connect the tubing in the order recommended on the illustration on the ISE tubing set cover.

When installing the single items, perform the individual steps in reverse order of removing the items.

■

► To install the new ISE unit tubing

1 Remove the new tubing set from its packaging.

Make sure to keep the piece of tubing designed to fit at the underside of the mixing tower. It will be required when a service representative performs periodic maintenance.

2 Place the tubing roughly in position on the ISE unit. Refer to the illustration on the ISE tubing set cover.

Take care not cut the tubing, avoid any sharp objects.

3 Press the tubes into their routing.

Take care not to compress the tubes or to kink them.

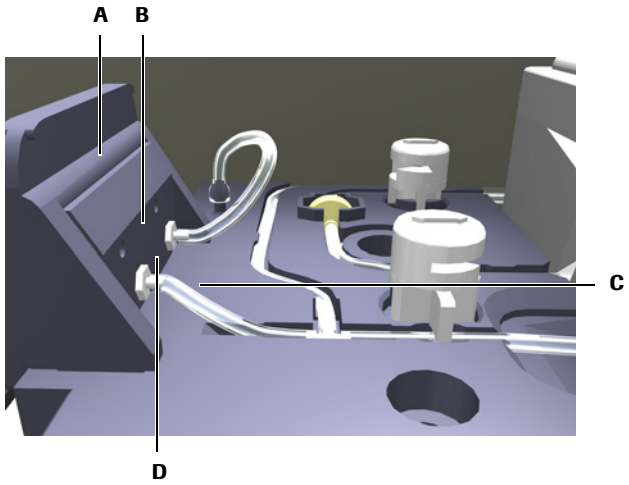
Make sure to press the tubing firmly in its routing around the ISE Reference Solution sensor.

4 Connect the tubing to the ISE tower and then install the tower.

5 After connecting the tubing to the electrode block, make sure the electrodes are properly mounted when closing the tension lever. Close the electrode block cover.

6 When connecting the tubing to the peristaltic pump connector block, take care not to introduce sharp angles in the tubing. (Sharp angles may lead to flow problems.)

Always insert the tubing connectors in the lower set of holes in the pump connector block, and make sure to fully insert the tubing in the connectors.



A Peristaltic pump block
B Upper set of sockets.
C There are no sharp angles in the tubing.
D Lower set of sockets.

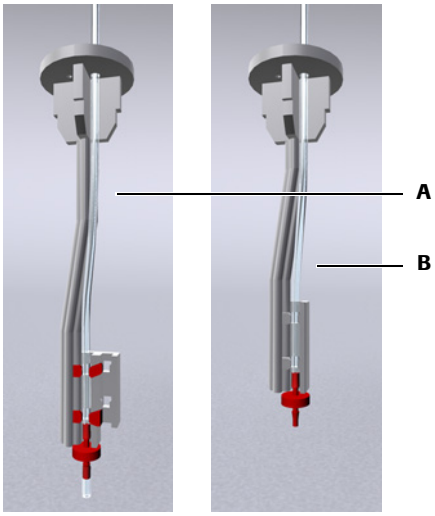
Figure E-16

7 Install all clamps and pinch valve caps. Be sure to place the clamps in the correct position, covering the tubing.

8 Install the lid of the fluid distributor.

9 Install the tubing on the tubing adapters of the ISE Calibrator indirect/urine and ISE Reference Solution bottles.

The two tubing adapters are slightly different, but the process of installing the tube is the same.



A ISE Reference Solution tubing adapter **B** ISE Calibrator indirect/urine tubing adapter

Figure E-17

- Pull the tube through the hole that aligns with the clips.
- Insert the nozzle in the tube.
- At the top of the adapter, pull through the tube until the nozzle is flush with the end of the adapter. There should be no slack.
- Fix the tube to the clips.

  With the adapter that offers two clip positions, use the inner position.
- Insert the tubing adapter in the appropriate bottle.

10 Close the ISE cover, then the left service flap and the main cover.

11 Press ✓ to confirm completion of the action.

Conditioning the tubing

The system now performs the maintenance action **Prime ISE Reference and Calib.**

A message will inform you when the maintenance action is complete.

The system now performs the maintenance action **Initialize ISE Reference Sensor.**

You are asked to remove the tubing adapter from of the ISE Reference Solution bottle.

12 Open the ISE cover.

13 Remove the tubing adapter from of the ISE Reference Solution bottle.

- Have a clean lint-free tissue ready.
- Lift the tubing adapter and place it on the tissue.

14 Press ✓ to confirm completion of the action.

The system now starts to initialize the ISE Reference Solution sensor.

You are asked to insert the tubing adapter in the ISE Reference Solution bottle and to close the ISE cover.

15 Insert the tubing adapter in the ISE Reference Solution bottle.

16 Close the ISE cover.

17 Press ✓.

The system first pumps ISE Reference Solution through the ISE tubing. Then it performs the **Condition ISE Tubing** maintenance action, and finally **Initialize ISE Unit**.

A message will inform you when the maintenance action is complete.

18 Remove the Activator from the sample area.

19 Press ⊗.

■

Deactivating the ISE unit

If you intend not to use the ISE unit for more than one week, you should deactivate it. This saves ISE fluids and reduces wear and tear of the tubing.

This situation may occur, for example, if you need close the laboratory temporarily, or if you want to relocate the **cobas c** 111 instrument with the ISE unit.

Tools and materials required

- ☐ Glass beaker
- ☐ Deionized water
- ☐ Tissues

Make sure that you have read and understood section *Safety information* on page E-42.

The following warning message in particular is relevant:

- *Injury through working solutions* on page E-42.
- *Infection by biohazardous materials* on page E-42

► To prepare the ISE data

1 Delete all ISE sample, calibration, and control results.

👁 See *Deleting sample results* on page B-94, *Deleting calibration results* on page B-95, *Deleting QC results* on page B-96.

2 Disable all ISE applications.

👁 See *Activating and deactivating applications* on page B-139.

3 Delete the ISE lot data.

👁 See *Lot handling* on page B-98.

► To deactivate the ISE unit

1 Open the ISE cover.

2 Remove the tubing adapters from the ISE solution bottles.

3 Place the adapters in a beaker filled with deionized water.

4 Remove bottles and screw on their lids.

5 Place the beaker in the position where your removed the ISE solution bottles from.

6 Choose **Utilities** > **Maintenance** > **Prime ISE Reference and Calib.**

7 Press ⏵.

The maintenance definition screen is displayed.

8 Press ✓ to start the action.

The ISE unit tubing is primed with water.

A message will inform you when the maintenance action is complete.

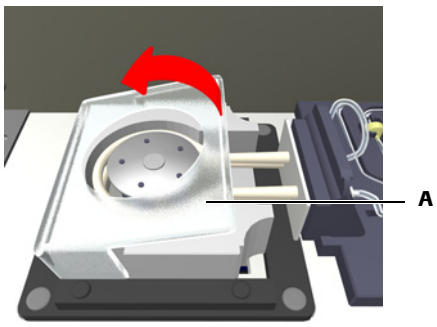
9 Repeat steps 6 through 8.

10 Remove the adapters from the beaker and place them on a lint-free tissue.

11 Repeat steps 6 through 8.

The water is drained from the ISE unit tubing.

12 Open the cover of the peristaltic pump.

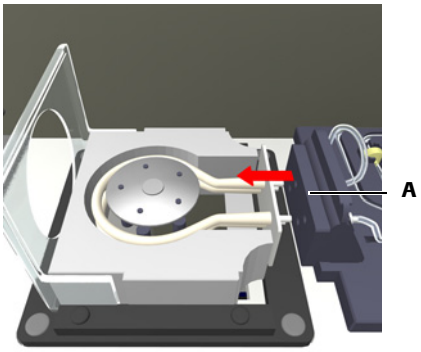


A Cover of peristaltic pump

Figure E-18

13 Push the pump towards the back of the instrument.

14 Disengage the tube connector plate.



A Connector plate

Figure E-19

15 Remove all pinch valve caps and clamps, store them in secure place.

See *Removing the pinch valve caps and clamps* on page E-58.

16 Close the ISE cover.

17 Switch off instrument.

18 Disconnect the ISE power supply from the wall socket.

19 Switch on instrument.

On the **Overview** tab, the ISE icon is deactivated (grey).

■

ISE troubleshooting

How to deal with exceptional ISE situations

In this chapter, you will find information on the result flags that may be generated with ISE measurements, and also guidance for general troubleshooting procedures and on how to deal with error messages.

In this chapter *Chapter* 15

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Introduction

Effective troubleshooting on the ISE unit requires a good understanding of all basic operating procedures. However, you can avoid most of the common problems if you observe the recommended procedures at all times and if the operating environment is effectively controlled.

For information on ISE maintenance, see *ISE maintenance actions* on page E-42.

Information about the ISE unit status

The user interface keeps you informed about the status of the ISE unit as a whole, and about particular hardware, software, and chemistry events as they arise. It does this in the following ways:

- Color coded LEDs on the instrument inform you when to open covers or place sample tubes.

  See *Color concept* on page A-74.
- The colors of buttons tell you whether you need to intervene.

  You can check the meaning of a button and its color using the Online Help .
- Buttons on the **Overview** tab lead to detailed information on the status of selected processes and hardware items.
- Messages on the screen provide information on individual tasks and events.
- The text in the Status line provides information on the status and activities of the analyzer unit.
- Flags with results from samples, calibrations, and controls are automatically generated if during processing certain technical checks were not passed or if the result exceeds or does not reach predefined limits.

Messages

The system performs numerous checks. When an irregularity is detected, an alarm message is generated. Alarm messages are displayed in two ways:

- Immediate feedback on user actions is displayed in a *pop-up message screen*.
- Information concerning a problem that occurred during operation is reported in the *Alarm Monitor*.

For details on alarm messages, see *Alarm monitor* on page D-6.
For details on instrument messages, see *Message screen* on page D-5.

Safety

Before you start troubleshooting, it is essential that you both read and understand the safety information listed below.

Read carefully all safety notices given in instructions and make sure you understand them.

WARNING

Injury through working solutions

Direct contact with cleaning solutions or other working solutions may cause personal injury. When handling such solutions, exercise the precautions required for handling them, observe the cautions given in the package insert, and observe the information given in the Safety Data Sheets available for Roche Diagnostics cleaning solutions.

Infection by biohazardous materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with protective gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If waste solution contacts your skin, wash it off immediately with water and apply a disinfectant. Consult a physician.

Injury or damage to the analyzer due to contact with instrument mechanism

Do not touch any parts of the instrument other than those specified. During operation and maintenance of the instrument, proceed according to the instructions.

Incorrect results or damage to the analyzer due to wrong operation

Operators are required to have a profound knowledge of relevant guidelines and norms as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Start all maintenance actions on the screen. Do not perform maintenance actions without the assistance of the user interface.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to trained Roche Technical Support personnel.
- Follow standard laboratory practices, especially when working with biohazard material.

List of ISE flags

This section lists the general and ISE-specific flags in alphabetic order and provides information on each of the flags.

For information on flags that concern absorbance measurements only, see *List of flags* on page D-28.

Where a flag description gives a list of recommended actions, work through each step in turn until you have solved the problem. Proceed to the next step only after you have completed the previous one.

>

Meaning Result generated by re-performing the test with the same running parameters (repeated).

Message ID 120

Priority 32

Possible cause The user initiated the repeat.

Recommended actions No action required.

Air Fluid

Meaning
- The length of the sample segment was too short.
- The end of the sample segment was not detected. It takes too long for a sample segment to reach the electrodes.

Message ID 19

Priority 4

Possible cause
- Air bubbles are present.
- The ISE tower is clogged.
- The dosing from the sample probes is inaccurate.
- The ISE tubing is leaking, blocked, or not conditioned.
- Mixing is too vigorous.

Recommended actions
- Check the quality of the sample.
- Check the sample tubes.
- Check the ISE tower and ISE tubing for leaks and blockages.
- Repeat the measurement.

Air Isecal

Meaning
- The length of the calibrator segment was too short.
- The end of the calibrator segment was not detected. It takes too long for a calibrator segment to reach the electrodes.

Message ID 91

Priority 5

Possible cause
- Air bubbles are present.
- The ISE tubing is leaking or blocked.

Recommended actions
- Ensure that the ISE Calibrator indirect/urine on the ISE unit is available and check the level of fluid; replace if necessary.
- Repeat the measurement.
- Check the ISE tubing for leaks and blockages.

? Cal

Meaning A result where its calibration is flagged.

Message ID 110

Priority 29

Possible cause The calibration was in question and has been flagged, however the calibration could be used to calculate the result (compare with Cal Error where the calibration did not provide a usable result).

Recommended actions Check and redo calibration if needed.

Cal Error

Meaning No valid calibration data available.

Message ID 43

Priority 24

Possible cause Caused by an alarm that occurred during calibration because the calibration could not provide a usable result.

Recommended actions Check the flags of the calibration and proceed to deal with the calibration first.

Calc Error

Meaning Calculation error.

- General calculation error.
- Slope or nonlinear standard curve cannot be calculated due to a calibration error.

Message ID 16

Priority 13

Possible cause

- Calibrator outdated or deteriorated.
- Misplacement of the calibrator tubes.

Recommended actions

- Repeat calibration with fresh calibrators.
- If the calibrators were incorrectly positioned, replace the calibrators and repeat the calibration.

Ise Unstab

Meaning The signal from the electrode(s) was not stable during the measurement.

Message ID 18

Priority 6

Possible cause

- There are air bubbles in the measuring segment.
- The concentration of sample is too low (for example, dialyzed samples).
- The ISE Reference Solution tubing is blocked or leaking.
- The pH of the sample is too low (for example, pH < 5.5).
- One or more O-rings are missing or damaged.
- There are salt deposits or there is an obstruction at the adapter of the ISE Reference Solution bottle.
- The electrodes have not been serviced.
- The expiration date of the electrode has expired or the electrode is damaged.
- The electrodes and/or the electrode block is not dry.
- The preamplifier is defective.

Recommended actions

1. Perform the maintenance action **Electrode Service** and repeat the measurement.
2. Repeat the measurement with a suitable sample (where pH > 5.5 and sample concentration within the test range) to establish that the ISE module is OK.
3. Check the position and condition of the O-rings and replace if necessary.
4. Check the adapter of the ISE Reference Solution bottle for salt deposits and obstruction.

No Fluid

Meaning The ISE sample or ISE Reference Solution sensor could not detect any fluid. It takes too long for a sample segment to reach the electrodes.

Message ID 68

Priority 2

Possible cause
- The fluid was not pipetted.
- The ISE tower is clogged.
- The ISE tubing is blocked or leaking.
- The ISE sample sensor is defective.
- The ISE Electrodes are blocked or not properly mounted.

Recommended actions
1. Repeat the measurement.
2. Check the sample tubing for clots.
3. Check ISE Electrodes and O-Rings for proper mounting.
4. Check the ISE tower and ISE tubing for leaks and blockages.
5. Ensure that the ISE bottles on the ISE unit are available and check the level of fluid; replace if necessary.

No Isecal

Meaning The ISE sample sensor could not detect any calibrator. It takes too long for a calibrator segment to reach the electrodes.

Message ID 90

Priority 3

Possible cause
- ISE Calibrator indirect/urine bottle is not available.
- The ISE tubing is leaking or blocked.
- The ISE sample sensor is defect.

Recommended actions
1. Repeat the measurement.
2. Ensure that the ISE Calibrator indirect/urine on the ISE unit is available and check the level of fluid; replace if necessary

Out of Rng

Meaning Slope out of range.

The slope for the specified electrode is outside the acceptable/programmed range.

Message ID 20

Priority 15

Possible cause This flag appears with calibrations because:

- There are problems with the ISE solutions on the instrument.
- There are problems with the electrodes or the ISE unit was not properly serviced.
- The ISE Reference Solution tubing is blocked or leaking.
- The dosing from the sample probe is not accurate.
- The preamplifier is not working properly.

Recommended actions If only one calibration is flagged:

1. Repeat the calibration.
2. Repeat the calibration with fresh ISE Solutions 1 and 2, and check visually the correct flow of all ISE solutions and the ISE Reference Solution.

If successive calibrations are flagged:

1. Repeat the calibration with fresh ISE Solutions 1 and 2, and check visually the correct flow of all ISE solutions and the ISE Reference Solution.
2. Check whether the electrode expiration date has expired. Replace the electrodes, if necessary.
3. Perform the maintenance action **Electrode Service**.
4. Perform the maintenance action **Deproteinize Probes**.
5. Check ISE Reference Solution tubing for leaks and blockages.
6. If the slopes of all electrodes are zero, replace the ISE Reference Electrode.
7. Contact your service representative.

? QC

Meaning A result where the quality control measurement is flagged.

Message ID 111

Priority 30

Possible cause The last QC measurement before this measurement was flagged. The dependency is derived from the time sequence.

Recommended actions Check QC measurement.

R 1(2.5s)

Meaning One control value is above 2.5 standard deviation or below -2.5 standard deviation.

Message ID 36

Priority 28

Possible cause
- The reagent has deteriorated (linearity of working curve degraded).
- One control is concentrated or has deteriorated.

Recommended actions
1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check the calibration and reagent status. Repeat with fresh reagent.

R 1(3s)

Meaning One control value is above 3 standard deviation or below -3 standard deviation.

Message ID 35

Priority 27

Possible cause
- Improper control is set.
- Proper control values (mean value, standard deviation) are not specified.

Recommended actions
1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check the calibration and reagent status. Repeat with fresh reagent.

>R 2(2s)

Meaning Two sequential control measurements are above the 2 standard deviation.

Message ID 29

Priority 26

Possible cause
- The controls are not properly prepared.
- The controls are not properly positioned on the instrument.

Recommended actions
1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check the calibration and reagent status. Repeat with fresh reagent.

<R 2(2s)

Meaning Two sequential control measurements are below the -2 standard deviation.

Message ID 29

Priority 26

Possible cause
- The controls are not properly prepared.
- The controls are not properly positioned on the instrument.

Recommended actions
1. Repeat with fresh control.
2. Check that the correct control material has been used.
3. If the flag reappears, check the calibration and reagent status. Repeat with fresh reagent.

> RR

Meaning Above reference range.

For patient samples, the calculated concentration is greater than the upper limit of the expected value range.

nnnnn is the actual value that was checked against.

Message ID 40

Priority 22

Recommended actions No action required.

< RR

Meaning Below reference range.

For patient samples, the calculated concentration is less than the lower limit of the expected value range.

nnnnn is the actual value that was checked against.

Message ID 41

Priority 23

Recommended actions No action required.

Seg Fluid

See *Air Fluid*.

Seg Isecal

See *Air Isecal*.

Sol1 F Dev

Meaning The ISE Solution 1 factor was not within the expected range.

Message ID 22

Priority 18

Possible cause This flag occurs with calibrations because:

- The dosing from the sample probe is not accurate.
- The ISE tower is blocked or the mixing was not sufficient.
- There may be problems with the ISE unit tubing, the electrodes, or the ISE unit was not serviced properly.
- The ISE Calibrator indirect/urine has expired.
- ISE Solution 1 has expired.

Recommended actions If only one calibration is flagged:

- Repeat the calibration.

If successive calibrations are flagged:

- Check whether the ISE Calibrator indirect/urine is in the correct position.
- Check whether the ISE Calibrator indirect/urine has expired.
- Check whether the ISE Solution 1 has expired.
- Perform the maintenance action **Clean ISE Tower Automatically**.
- Perform the maintenance action **Activate Electrodes**.
- Perform the maintenance action **Deproteinize Probe**.
- Perform the maintenance action **Prime ISE Calibrator & Reference**.
- Check whether the electrode expiration date has passed. Replace the expired electrode, if necessary, and perform the maintenance action **Electrode Service**.
- Check the ISE unit tubing for leaks and blockages.
- Contact your service representative.

> Test Rng

Meaning PANIC value over (upper) Technical Limit.
The result is higher than the upper limit for the test.

Message ID 26

Priority 20

< Test Rng

Meaning PANIC value below (lower) Technical Limit.
The result is lower than the lowest limit for the test.

Message ID 27

Priority 21

Reacting to error messages

For general information on error messages and troubleshooting, see *Reacting to messages* on page D-44.

The following table lists selected messages and provides more detailed information on how to react to them.

Message or error code	Affected items	Possible causes	Comments
[8.xxx.56] The ISE reference sensor has detected too much air during ISE Reference Solution transport.	ISE unit.	ISE Reference Solution is empty.	Replace the ISE Reference Solution bottle. See *Replacing ISE fluid bottles* on page E-30.
		Leakage in the tubing or at electrodes.	• Check that the ISE unit tubing is properly connected. • Check the ISE unit tubing for leakages and blockages. See *Replace ISE unit tubing* on page E-57. • Check that the electrodes are mounted properly. See *Replacing electrodes* on page E-32.
		The cover of the peristaltic pump is open or not properly closed.	Close the cover.
		The tubing around the ISE Reference Solution sensor is not properly installed.	Make sure that the tubing is properly pressed into the groves and that the tubing itself is not compressed.
[109000567] code raised by IC software caused by an unexpected handling or system situation.	ISE unit.	This is a flow problem within the ISE unit, the ISE tower is not empty. The system checks whether the tower is empty before dispensing.	Perform the following checks: • Check that the ISE unit tubing is properly connected. • Check the ISE unit tubing for leakages and blockages. • Check that the electrodes are mounted properly. • Check that the pinch valve caps and clamps are properly installed. • Check that the peristaltic pump cover is properly closed. See *Replace ISE unit tubing* on page E-57.

Figure E-20 ISE troubleshooting with the help of messages

Glossary and Index F

Glossary *F-3*
Index *F-11*

Glossary

This glossary is a compendium in which to look up the meaning of technical terms used in conjunction with the **cobas c** 111 instrument.

Numbers

2-dimensional barcode A type of barcode on reagent bottles, calibrators, and control barcode sheets. These matrix barcodes, which use PDF417 symbology, contain more information than traditional linear barcodes.

A

absorbance photometer A device used to make absorbance photometry measurements. It consists of a halogen light source, optical groupings, a monochromator (diffraction grating), a preamplifier, filters, and a diode array. See also photometer.

accuracy The absolute deviation of a result from a pre-defined target value in percent or absolute units.

activate The process of conditioning electrodes with fresh serum so that the correct potentials are measured.

Activator Serum used to coat ISE electrodes, tubing and the sample probe after cleaning procedures. (The **cobas c** 111 Activator is based on human sample material. For further details refer to the Activator package insert.)

alarm A visual or audible operator notification of any system irregularity.

Alarm button A button used to display the alarm messages.

alarm level A level that identifies the source and severity of a problem. There are two levels: warning, and alarm.

alarm message A message that reports a system irregularity. It can be viewed in the alarm monitor screen. See Alarm button.

aliquot Portion of sample material pipetted into any secondary cup.

alphanumeric sorting The listing of information, in a printout or on a screen, in a pre-defined order by letters or numbers.

analyte The constituent in the sample that is to be determined.

analytical instrument A device or a combination of devices used to carry out an analytical process.

analyzer unit Central analyzing unit including cooling assembly, heating channel, rotor and insulation. Does not include the photometer unit.

application Chemistry and method to determine a parameter. See also test.

assay 1. A specific test.
2. The process of measuring a substance.

B

backup The saving of data onto supplementary storage media such as disks or tape. If such data is required again but is no longer available from the main storage (instrument hard disk), it can be restored from a backup copy.

barcode A numeric or alphanumeric code used on sample tubes and reagent bottles to identify the samples and reagents. Different barcode standards are available. See also barcode type.

barcode scan The process of reading barcode information into the memory of an instrument.

barcode scanner The device that reads the code from sample or reagent barcode labels.

barcode transfer sheet (BTS) A sheet bearing a barcode that encodes test-related (or calibrator or control) information for an analytical instrument.

barcode type Typical sample barcode types used in the IVD industry are Code39, NW7 (Codabar), ITF, and Code 128.

biohazardous A classification used to identify material that poses a health threat, for example something contaminated with biological material.

button A button is found on a screen or pop-up window. It can be touched either to initiate an action or to move to a different screen.

C

calculated result A test result calculated from different individual analytical methods with a given formula such as ratio A/B.

calibration The set of operations that establish, under specified conditions, the relationship between values indicated by the analytical instrument and the corresponding known values of an analyte.

calibration interval A specified interval at which an assay should be calibrated. Typically found on reagent package inserts.

calibration type Describes the event that triggers the calibration, for example lot change, and interval expiration.

calibrator 1. A material of known composition or properties that can be presented to the analytical instrument for calibration purposes.
2. The test portion or test solution used for calibration of an analytical procedure.

carryover A process by which materials are carried into a reaction mixture where they do not belong.

check digit A verification number used in barcodes and software.

check sum The result of a mathematical procedure to validate the integrity of a set of data.

cleaner A solution used to wash the probe.

clot detection 1. A device built into the pipetting system to detect clots and to avoid false pipetting.
2. The procedure of detecting a clot.

cobas A modular range of in vitro diagnostics systems from Roche Diagnostics/Hitachi High-Technologies.

communication The exchange of data between different computers.

conditioning The process of letting serum-type liquid flow through the flow path before electrolyte measurement.

consumables A generic term for items that are used during test processing and must be replaced on a regular basis by the operator. Examples of consumables include printer paper and cuvette segments.

control See control material.

control ID The abbreviated name for a control material. Control IDs are used on screens where limited space prevents the use of longer names.

control material A material used to assess the performance of an analytical procedure or part of an analytical procedure. Also called the control sample.

control name The name of a control material, for example PreciControl Universal.

CPU The Central Processing Unit of the system or computer.

CSF Abbreviation for cerebral spinal fluid. A sample type for clinical analysis.

cup See sample cup.

cup-on-tube The placement of a smaller secondary sample container (for example a Hitachi Cup) on top of a primary sample tube.

cuvette Disposable plastic container into which sample, reagents, diluent, and water is pipetted, and where the sample pre-dilution and reaction takes place.

cuvette port Section of the analyzer unit where cuvette segments are inserted and removed.

cuvette segment Cuvette holder containing 10 cuvettes.

cycle The instrument time interval during which pipetting or measurement can be carried out.

D

DAT Abbreviation for Drugs of Abuse Testing. The abbreviation DAU is also used.

database A defined section of the computer memory where all instrument, assay, and patient-relevant data are processed and stored.

DAU Drug of Abuse in Urine. The old term for DAT or Drugs of Abuse Testing.

DB Abbreviation for database.

DBMS Abbreviation for database management system.

dead volume The amount of residual sample material in a sample tube or cup.

default QC An automated process for performing multiple QC measurements at the time when you define the QC orders.

default value A set value registered in advance (initial setting).

demographics Patient-related data such as name, date of birth, and gender.

diluent (DIL) A liquid agent used to reduce the concentration of a sample.

dilution factor A preset dilution ratio that is used by the analyzer to perform a requested dilution.

disposable Typically a plastic tip, vessel, or cuvette that is discarded after a single use.

dynamic range The reportable range of an assay. This range extends from the lower detection limit to the limit of linearity.

E

E-stopped A status indicating that the system has performed an emergency stop. This could be due to hardware failure or because any of the safety devices have requested an emergency stop.

expected range The pre-defined range of test result values expected for a defined group of healthy patients or materials. Also known as *normal* range or *reference* range.

expected value A value for a test result that can be considered as a *normal* result.

expiration date Also called the expiry date. The end of a period until which Roche Diagnostics guarantees product claims for its reagents, calibrators, and controls.

extended dynamic range The measuring range for an assay at its highest dilution.

F

filter A process that sorts data for viewing, documenting, or printing according to pre-defined criteria

flag An identifier used to call an operator's attention to a result.

G

global action button See global button.

global button A button that allows access to the global software screens and that can be used at any time. For example, <Start>, <Stop>, or <Alarm>.

H

home position The position to which a certain part of the instrument returns on reset. The start position of a mechanism.

host computer 1. A computer used for overall management and control of the computer network. 2. A clinical laboratory computer that stores and processes patient requests and results. A host is able to communicate with analytical instruments.

host communication Data exchange with a clinical laboratory information system (LIS).

host interface protocol A technical description that defines data transfer between a host computer and an analytical system.

I

Initialization Also known as Initializing. The operational mode of an analyzer that occurs immediately after power on and during which the instrument prepares itself for operation.

installing applications Process of making the application available for testing, as opposed to importing the application data, which just saves the data on the system.

interval QC A streamlined process of performing (all) due QC measurements (for QC that needs to be performed periodically.)

ISE Abbreviation for ion-selective electrode.

ISE Reference Electrode The electrode through which the ISE Reference Solution flows to set the electronic baseline to zero for ISE measurement.

ISE Reference Solution A KCl solution pulled through the ISE Reference Electrode to set the electronic baseline to zero for ISE measurement. Also known as the REF or reference electrode solution.

IVD Abbreviation for in vitro diagnostics. A diagnostic procedure performed outside the living body with specimen body fluid.

L

level detection A check for the availability of sufficient liquid in a container.

linear barcode A conventional one-dimensional barcode with limited data capacity.

liquid level detection (LLD) The ability of an analytical instrument to sense liquid by using the probe.

log file A set of data, typically stored in the control unit, that traces instrument-related or operator-related activities such as maintenance.

log off The procedure of terminating access to a system. Also known as log out or logoff. The reverse procedure is known as log on or log in.

Log off button A button used to terminate access to a system. See also log off.

log on The procedure of gaining access to a system by entering a user name and, if required, a password. Also known as log in or logon. The reverse procedure is known as log off or log out.

Log on button A button used to gain access to a system. See also log on.

lot calibration A mandatory calibration when a new lot of reagents is introduced to an analytical instrument.

M

main calibration Two-point calibration of the ISE tests with ISE Solution 1 and 2. (As opposed to the calibration with ISE Calibrator indirect/urine, which is part of each ISE measurement.)

maintenance action A maintenance procedure performed by the system or the operator; and that must be performed on a regular basis (for example daily, weekly, or monthly) to secure reliable operation of the analyzer.

maintenance procedure See maintenance action.

manual dilution An off-system, pre-analytical step performed by laboratory staff to reduce the analyte concentration in a sample.

mean The sum of values divided by the number of values.

measure point Time at which absorbance reading is taken and used to calculate results.

measuring range See reportable range.

message In computing, a defined set of alphanumeric data that transfers information from computer to computer or from an analytical instrument to the operator.

Microcup A secondary sample cup made by Hitachi with a small dead (residual) volume.

minimum sample volume The amount of residual sample material plus the volume required for assaying all requested tests to ensure faultless sample aspiration.

monochromatic Absorbance measurement at one (primary) wavelength.

multi-wavelength spectrophotometer A spectrophotometer in which detectors are placed at multi-wavelength positions to enable simultaneous light reception.

O

on-board 1. A technical device or function that is part of the analytical instrument and can be used by the instrument at any time.
2. The availability of reagents and consumables on an analytical instrument for use at any time.

online help On-screen documentation that a user can request in a context-sensitive manner.

operating system A software program that controls all basic functions of a computer (for example, Windows, Linux, and Palm OS).

operator The person who uses and controls the analytical instrument or a computer system.
See also user.

operator ID An alphanumeric ID that a system uses to identify a particular operator.

order Collection of all tests that are defined to be performed for a particular sample.

order ID A set of alphanumeric data that unmistakably identifies a particular sample order in the lab and is often manually written on the sample label.

P

parameters A set of criteria or definitions used to establish how an assay is performed. Examples of parameters include sample and reagent volumes and incubation times and temperatures. Such information is typically contained in the application definitions and cannot be changed by the operator.

password A form of authentication that uses secret data to control access to a resource.

photometer A device that measures the intensity of light.

photometer unit Complete photometer assembly, including optical components, power supply, preamplifyer and absorbance controller.

pipette (to ...) The process of aspirating and dispensing sample and reagents, performed by an appropriate probe.

pop-up screen A screen that contains additional information or additional options required for making entries or decisions.

potentiometric assay An assay in which analytes (for example Na, K, or Cl) are measured by ion-selective electrodes.

precision The closeness of agreement between independent test results obtained under prescribed conditions.

pre-dilution A dilution step performed before samples are analytically processed on the analyzer.

preventive maintenance A series of actions, suggested by the system, that the operator should perform to ensure smooth and uninterrupted operation of the instrument (for example, emptying the waste container or replenishing reagents).

primary tube The original tube containing the sample that has been drawn from the patient.
See sample tube.

prime The process of flushing a system, for example the tubing, with ISE Calibrator indirect/urine and water to clear it of possible obstacles, traces of fluid, and of air bubbles.

profile A user-defined set of tests.

protocol 1. A convention or standard that controls or enables the connection, communication, and data transfer between two computing end points. Protocols can be implemented by hardware, software, or a combination of the two.
2. A set of rules that guides how an activity should be performed.

Q

QC Abbreviation for quality control. The operational techniques and activities that are used to fulfill requirements for quality.

QC measurement The process of performing a test with control material.

query download A communication process between instrument PC and LIS by which a pre-defined data set is transmitted upon request of the analytical instrument.

R

RAM Abbreviation for random access memory. Semiconductor memory devices used in computers. RAM content is lost when a computer is switched off.

ratio A test result calculated from different individual analytical methods with a given formula such as A/B.

raw data The unprocessed values obtained during the analytical process on an instrument (for example mVolt or absorbance).

reagent A composition of chemicals used to determine the concentration of substances in body fluid.

reagent bottle Standard plastic bottle for photometric reagents.

reagent disk The removable device into which the reagent bottles are placed.

reagent disk position One of the multiple positions on the reagent disk.

reagent port Section of the analyzer unit where reagent bottles are inserted and removed.

reference electrode See ISE Reference Electrode.

reference range See expected range.

reference solution See ISE Reference Solution.

repeat The performance of the same test on a sample again with identical dilution.

reportable range The range of results that can be reported for the assay. It stretches from the lower detection limit to the high end of the calibration curve.

request See order.

rerun The performance of the same test on a sample again with a different dilution.

result The value reported by an analytical device during or after the assay of a sample or control.

ROM Abbreviation for read-only memory. Semiconductor memory devices used in computers. ROM content remains when a computer is switched off.

rotor Assembly consisting of cuvette ring and plastic frame.

S

sample area Area on the instrument where sample tubes are placed.

sample cup A small container that is used for samples and also for calibrator and control material. A sample cup can be placed either directly on the sample area, or on sample tubes. Compared to a sample tube, a sample cup allows the use of smaller liquid volumes and so reduces the dead volume.

sample ID A set of alphanumeric data that unmistakably identifies a particular sample within a whole organization, for example the hospital. It is used on barcodes and is the unique identifier used to communicate with a laboratory information system.

sample splitting The act of making one or more aliquots from a primary or secondary specimen.

sample tube A glass or plastic container for liquid samples to be used with the system. It may or may not have a bar code label, which may be used for positive sample identification. A sample tube contains sample of one specific specimen (sample) type.

sample type A type of sample that can be analyzed: serum, plasma, whole blood, or urine.

sampling stop An alarm level that indicates a problem with the sampling system.
See also S.Stop.

scan See barcode scan.

scroll The action of moving through text or graphics (up, down, left, or right) to see parts of the file or list that cannot fit on the screen.

scroll arrow An arrow on either end of a scroll bar that you use to scroll through the contents of the screen or list box.

scroll bar A bar that appears at the bottom or right edge of a screen whose contents are not entirely visible.

SD Abbreviation for standard deviation.

secondary tube A sample container of variable size into which aliquots are transferred.

shutdown The process of powering off an instrument.

software A computer-operated program that processes data in a defined manner. Software is usually intellectual property of the software supplier or its licensee.

specimen Generic term for a calibrator, control and sample.

standard Traceable reference material used to create the master calibration curve.

standard deviation A statistic used as a measure of the dispersion or variation in a distribution of data.

Start button A button used to start system operation (Operating status) and begin the pipetting of samples, measurement, and the result calculation process.

STAT Abbreviation for Short Turn Around Time. Terminology used by the medical clinical professionals to prioritize the processing of a sample in a laboratory.

status A general term used to refer to the current status of the system. Explicit terminology may be used to address sub-parts of the system status (such as analyzer status and printer status).

Stop button A button used to display options for different kinds of processing stop.

SW Abbreviation for software.

T

target range The allowed range of recovery for an analyte in a control material.

target value The mean of all participant responses after removal of outlying values.

TAS Abbreviation for Test Application Software.

TDM Abbreviation for Therapeutic Drug Monitoring.

test Running an analysis of a specific parameter for a sample. See also application.

test ID The abbreviated name for a test. This code is displayed on test buttons shown on screens.

test sheet A document that lists all the information necessary to perform a specific assay or test on an instrument.

touchscreen An input device that allows the user to interact with the computer by touching the display screen.

turn-around-time 1. The time between the decision to perform a test and the time when the doctor receives the result and can act on it.
2. Inside the laboratory (Lab-TAT): Time between receiving a sample and sending out the validated result.

U

unit A chosen reference quantity of an analyte used to compare quantities of the same dimension (for example, mol/L, g/L, or U/L).

user The person who operates and controls the analytical instrument or a computer system.
See also operator.

user interface The part of a system exposed to a user. In a computer system, the user typically interacts with an operating system or with application software. With these the user interacts by using menus, icons, keystrokes, mouse clicks, and similar means.

V

validation The process of checking results or data against defined rules or ranges in clinical laboratories. Validation can be against technical or clinical criteria.

W

waste Anything discarded by the analyzer; waste can be liquid or solid.

worklist A report generated by an analytical instrument. A worklist aids a user by listing calibrators, controls, and samples currently loaded on the sample area.

worklist - worklist

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